Hope and hiv medication and adherence essay sample

Health & Medicine



Hope and hiv medication and adherence es... - Paper Example

Page 2

Abstract

The HIV pandemic continues to pose serious global threats. Even though

anti- HIV medications are now widely available, strict adherence to the

prescribed regimen is largely unsatisfactory. Hope could improve adherence

to these medications. The purpose of this two-group post-test only

randomized correlation study is to determine whether hope is related to HIV

medication adherence. We hypothesize that there is a relationship between

hope and adherence to HIV medication. The research will take place at the

Veteran Administration Medical Center's HIV Clinic, located in North East

United States and use will be made of the stratified sampling technique to

select the study subjects.

Subjects for this study will be HIV positive adults who have known their

status for at least 6 months and are currently on anti-retroviral medications.

The subjects will also be able to speak, read, and understand English.

Instruments to be used in this study will include the Herth Hope Index (HHI)

and the Brief Medication Questionnaire (BMQ). HHI will be used to determine

the levels of hope among the study subjects while the BMQ will be used to

assess the study subjects' adherence to medication. Validity and reliability

will be assessed through the Cronbach's alpha test and comparison of

baseline and t (60) CD4 counts with the survey outcomes. Tests of

significance will be performed using the independent t-test.

CHAPTER ONE: INTRODUCTION

Overview of the first chapter

https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-

sample/

This chapter is divided into ten sections. The first section comprises of a concise background of this study. Here, aspects of the entire study are broadly delineated and the framework for the study enumerated. Thereafter, the problem statement, which provides a brief outlay of the challenge at hand, is offered. The next section is the conceptual framework. Here, the self regulatory model (SRM) is identified as the theoretical framework which underpins the entire study. Subsequent sections focus on the theoretical assumptions made by the researcher, the research questions to be investigated as well as the significance of this study. The aims and objectives of this study are listed and hypotheses stated. Finally, the last section gives an account of the definitions of terms used in the study.

Background of the Study

sample/

Adherence to human immunodeficiency virus (HIV) medications is a critical factor for the successful treatment of this chronic illness. An adherence rate of less than 95% can impair these medications' effectiveness in constraining the replication of the virus. Besides, low adherence has also been noted to facilitate the ability of the human immunodeficiency virus to diversify thus creating strains that are resistant to immune suppression. As a result, the probability of secondary illness and progression to AIDS increases (Lewis, 2004).

Becoming immune to antiretroviral medications due to virus mutation may lead to resistance to all medications within that drug category (e. g. protease inhibitors), a process that is called cross-resistance. Cross-resistance can impede the further utilization of not just one, but a whole category of https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-

medications for treatment (Ickovics & Meade, 2002; Stone et al, 2004; Tennenberg, 1999 and Young, 2007).

The appropriate and effective use of drug therapy is vital to a reduction of morbidity and mortality for individuals living with Human Immunodeficiency Virus (HIV) infection. A major development in the treatment of HIV infection was the introduction of Highly Active Anti-Retroviral Therapy (HAART) in the mid 1990s. By the end of 2007, approximately, 36. 1 million persons worldwide were infected with HIV (World Health Organization [WHO], 2006).

The number of medications available for treatment has expanded remarkably since the identification of the disease. The first treatment strategy developed was to prevent viral replication, and, in 1985, the first class of drugs, nucleoside reverse transcriptase inhibitors (NRTIs), was studied. With the approval of the of the single-drug therapy zidovudine in 1987, researchers began to understand dose-limiting toxicities and the benefits of antiretroviral therapy (ART). During this time, many wondered whether this treatment should be offered when patients were being admitted to hospitals sick with fatal illnesses.

Initial reports showed that combination therapy with two nucleoside analogs was more effective than monotherapy in delaying the progression of the disease and death. In the following 8 years, three other NRTIs became available. Eight more medications were approved; including the introduction of two new classes called protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs). The term highly active ART, or HAART, was then introduced. The introduction of these medications led to https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

improved treatment of HIV infections in the United States, dramatic reductions in death rates and significant improvements in clinical outcomes (Johnson et al., 2003; Lewis Poppa et al., 2004; Thorner & Rosenberg, 2003; Reynolds, 2004; Zorilla et al., 2003).

Prior to the advent of HAART, median survival after infection with HIV ranged from 8 to 12 years (CASCADE, 2003; Palella et al., 1998). A conceptual shift from the view of HIV infection as an acute and terminal illness to one more closely aligned with a chronic illness model has accompanied the decrease in HIV-related morbidity and mortality following the introduction of HAART (Heckman, 2003; Mitchell & Linsk, 2004; Nixon & Renwick, 2003; Shernoff, 2002).

While the clinical benefits of HAART are well documented these outcomes are not obtained without considerable difficulty in many cases. The most critical factor in achieving clinical success with HAART is the ability to maintain almost perfect levels of adherence to often challenging drug regimens. Given the near perfect levels of adherence needed, it is not uncommon to find that sub-therapeutic levels of adherence are frequently exhibited by individuals on HAART (Arnsten et al., 2002; Bangsberg, Hecht, Charlebois, Chesney & Moss, 2001;).

Less than optimal levels of adherence to HAART can potentiate the development of drug resistant strains of HIV that can increase morbidity and mortality for infected individuals and, if transmitted to others, pose a serious threat to public health (Hecht et al., 1998; Reynolds, 2004; Yerly, Kaiser, Race, Bru, Clavel & Perrin, 1999). A significant amount of research has been https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

conducted to examine factors impacting individual adherence behavior. Some studies have demonstrated no predictive relationship between sociodemographic factors and adherence behavior in general (Eldred, Wu, Chaisson & Moore, 1998). Several studies of HIV sero-positive individuals, however, have demonstrated positive correlations between certain sociodemographic factors and adherence. These factors include male gender, white race, older age, higher income, higher education and literacy (Chesney, 2000; Chesney et al, 2000; Gifford et al, 2000; Kleeberger et al, 2001).

Several additional factors shown to be predictive of adherence include a strong medical provider-patient relationship, improved t-counts, lower viral load and emotional (social) support from peers (Gonzalez et al. 2004; Lewis & Abell, 2002; Ickovics & Meade, 2002). Barriers to adherence found in these studies include forgetfulness, drug and alcohol use, drug side effects, problems taking medication at work, problems with refills, depression, and psychiatric illness. Numerous studies have examined variables in clients experiencing treatment failure or having difficulty maintaining adherence to their regimen (Frick, Gal, Lane & Sewell, 1998; Kennedy, 2002; Roberts, 2000; Samet at al, 2000).

The majority of these studies have used heterogeneous samples as well as quantitative research methods. A shift in adherence research focuses more on individuals who are HIV positive and report high levels of adherence to their treatment. Few studies have focused specifically on individuals who

report high levels of adherence (Lewis, Colbert, Erland & Meyers, 2006; Malcom, Ng, Rosen & Stone, 2003).

Problem Statement

Adherence to HIV/AIDS medication is a core issue for the treatment and survival of infected individuals. Although the illness itself is now considered manageable when proper treatment protocols are followed, various issues have arisen both physiologically (side effects) and virologically (mutations) that add to and impact the ability to maintain successful treatments over time (Ickovics & Meade, 2002).

New medications have advanced both treatment availability and methodology. Since the early use of the single drug AZT, there are now five drug categories which include multiple combination and injection-type drugs available for use. Despite the pervasiveness of these medications and their role in the management of the disease, adherence to prescribed HIV medications remains less than satisfactory. Besides compromising the fight against the scourge, non-adherence suggests that other critical factors play a big role in influencing strict adherence to HIV medication.

The positive role of hope in human life, in health and illness, is widely recognized and is significant in nursing. The meaning of hope to humans has been described my many philosophers, theologians, psychologists, and nursing researchers (Day, 1991; Eriksson, 1989; Fromm, 1968; Marcel, 1962; Nores, 1992; Ross, 1994). Research from many different disciplines suggests that hope and despair are closely interwoven with health and illness. Hope is

considered an important coping strategy in the critical stages of human life (Obayuwana & Carter, 1982; Miller, 1983; Krause, 1993). In nursing science, many writers stressed the importance of hope on the part of the family of the sick person (Hickey, 1990; Koller, 1991).

Hence to find out if hope has an effect on medication adherence for the survival among HIV patients is an utmost importance. Understanding the reasons for the effect of hope in medication adherence is therefore a critical factor for creating and managing successful treatment.

Statement of Purpose

The purpose of this study will be to explore the relationship between hope and adherence in HIV patients who self- report success adhering to HAART. By examining the adherence behaviors of patients who report adherence it may be possible to discern relationship between hope and medication among these individuals. Strategies seen as supporting successful adherence behavior might be shared with individuals currently having difficulty with medication adherence. Hence, the main purpose of this study will be to determine whether hope has an effect on medication adherence in HIV patients.

Conceptual Framework

For this particular study, the conceptual framework is premised on the 'self regulation model (SRM) of coping with health threats'. This model was put forward by Leventhal et al (1984) and presupposes that cognitive representations of a health threat largely determine the coping mechanisms https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

which people adopt in order to assuage the threat faced. These coping mechanisms have an impact on the eventual physical and emotional outcomes in the persons faced with the said threat.

Assumptions

This study makes the following assumptions

- That the test instruments used in the study will accurately and consistently measure the phenomenon in question. In this regard, it is assumed that the three dimensions of hope namely interconnectedness, mortality and the future, and anticipation and positive preparedness are truly valid. It is also assumed that the three subscales of the BMQ scale accurately represent adherence Herth, 1991; (Svarstad, Chewning, Sleath and Claesson, 1999).
- That the respondents interviewed will gave responses that are accurate and precise
- That the tests of validity and reliability specified will eliminate all forms of bias
- That measures used to ensure data validity and reliability will be beyond reproach
- That the sampling method adopted will be free from errors

Research Questions

1. Is there a relationship between hope and adherence to HIV medication?

2. If there is a relationship between hope and adherence to HIV medication, what is the nature and extent of this relationship?

Significance Statement

Significance to Nursing

Studies investigating the relationship between the two variables are few and far in between. Godin, Gagne and Naccache (2003) studied non-adherence to ART medication among HIV patients in Canada using the BMQ. The aim of this prospective longitudinal study was to validate the BMQ instrument and the role of hope in adherence to medication was not investigated. Other studies have similarly asserted the validity of BMQ as a tool for measuring non-adherence among HIV patients (Deschamps et al, 2008; Muñoz-Moreno et al, 2007; Diabat et al, 2007 and Simoni et al, 2006). As such, data pertaining to the role of hope in adherence to medication among HIV patients is sorely lacking. This study will contribute to this gap in literature by defining the relationship between hope and adherence to medication among HIV patients.

This study is also significant to the field of nursing in the following way. It is envisaged that the study will provide a concise outlay of the common factors which reduce adherence to medication among HIV patients in the Veterans Medical Centre in the North East of America. Such factors will help In this way, nurses and other caregivers will be better equipped to help such patients take the prescribed medications with the desired regularity

Aims and Objectives

The Aims and objectives for the study will be:

1. Aim: To describe the medication adherence experiences of HIV patients who self- reported being adherent to their HAART regimen. This will be achieved through the following objective:

Objective 1: to administer the Brief Medical Questionnaire (BMQ) on the selected population and assess the obtained responses

2. Aim: To describe whether hope has an effect on medication adherence in HIV patients. This will be achieved through the following objective:

Objective 2: to administer the Herth Hope Index on the selected population and assess the obtained responses

Hypotheses

Alternative Hypothesis

There is a relationship between hope and adherence to medication in HIV patients

Null hypothesis

There is no relationship between hope and adherence to medication in HIV patients

Definition of Terms

Terms that will be utilized in this study include:

- 1. Adherence (medication compliance): taking medications as prescribed by treating physician(s) without missing or in any way altering the dosage (HRSA, 2005; Thomson PDR, 2003). Herein acceptable adherence is considered as taking medication at least 95% as prescribed.
- 2. Antiretroviral medications: medications whose purpose is to impede or in some way interfere with the HIV virus ability to infect t-lymphocyte (CD4) cells and replicate its own DNA to reproduce itself. The major medication categories include nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and injectable cell fusion inhibitors (Fuzeon) (Thomson PDR, 2003). 3. HAART: highly active antiretroviral combination of antiretroviral medications therapy utilizina а simultaneously (Thomson PDR, 2003, PADOH, 2004).
- 3. HIV/AIDS: human immunodeficiency virus / acquired immunodeficiency syndrome. The virus attaches to and attacks CD4 immune cells leading to failure of the body's natural immune system. AIDS is a diagnosis given when an individual's immune (CD4) cells drop below 200 cells /microliter (PADOH, 2004).
- 4. Medication compliance (adherence): taking medications as prescribed without interruption.
- 5. Medication failure: the inability of the medications to function effectively as designed. This may be due to virus mutation making the medication ineffective or due to medication non-adherence on the part of the patient (Thomson PDR, 2003).

- 6. Non-adherence: failure to take medications as prescribed.
- 7. Resistance: the inability of the medications to function effectively which may be due to medication failure or viral mutation (Thomson PDR, 2003).

CHAPTER TWO: LITERATURE REVIEW

Behaviors can factor high for non-adherence and may include a range of causes from simply forgetting to consistently take HIV medications to work site issues. These factors make it awkward to discreetly carry or take doses as scheduled. Other individuals follow social interaction schedules that make dosing times inconvenient for them (e. g. dating, family events, being with friends).

A study by Heckman et al (2004) assessed the Chronic Illness Quality of Life (CIQOL) Model. The objective of this study was to appraise the factors that contribute to life satisfaction among HIV positive patients. The study had 329 participants from rural areas in 12 states. There were 237 males and 92 females, ages 18 to 70. The study utilized participants from small communities with populations under 10, 000. The AIDS Clinical Trials Group (ACTG) Adherence questionnaire was utilized and a \$30 incentive was offered for those completing the survey. This study particularly addressed the issue of geographically rural HIV-infected individuals versus urban/metropolitan (over 10, 000 population) areas.

Univariate, multivariate, and regression analysis results of the study showed 15% reported missing medications due to forgetting, 15% had problems with the dosing times, and 12% (in each category) experienced side effects, felt https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

sick, or were depressed. Alcohol or substance use during the previous two months was not highly associated with non-adherence, and 10% reported deviating from once-daily dosing. Fifty percent reported less than 100% adherence. Demographic issues such as ethnicity, et al, were not shown to correlate with non-adherence.

In a study by Reynolds, et al (2004), 980 participants completed an AIDS Clinical Trials Group (ACTG) Adherence questionnaire as part of an overall study of factors influencing medication adherence. Participants were 799 male and 181 female ranging in age from 13 to 50. Results of analysis showed that 33% simply forgot to take their medications, 27% missed does due to being away from home, and 26% missed due to being too busy to dose. The least given reason was not wanting others to notice (10%).

This study focused on behavioral characteristics and did not report for substance use or medication side effects. The study also reported that it appeared that half the participants failed to adhere to dosing as directed, and the authors suggested additional studies to ascertain non-adherence factors in more detail. In a study by Murphy, Roberts, Martin, Marelich, & Hoffman (2002), 39 participants completed an AIDS Clinical Trials Group (ACTG) Adherence baseline questionnaire as part of the study. Adherence for the week prior to the study was reported at 33% adherent (> 95% being optimum) while 8% reported little or no adherence. The 27 males and 12 females in the study were on an average of 15 pills per day. The six most reported reasons for non-adherence were sleeping through dose times (53%), problems taking pills with special instructions (50%), changes in daily

routines (47%), not having medications with them (42%), being too busy to stop for dosing (42%), and simply forgetting to take the doses (40%).

Among the psychosocial factors found to impact adherence behavior are active drug or alcohol use, concerns about weight or body image, psychiatric illness, self efficacy, social support, positive state of mind (PSOM) defined as an individual's capacity to enter positive cognitive and interpersonal states, and routinization of daily behaviors (Gonzalez, et al., 2004; Stein, Rich, Maksad, Chen & Hu, 2000; Tucker et al., 2004; Wagner & Ryan, 2004;). Chesney (2000) also demonstrated that the ability to identify medication and treatment regimen and an understanding of the relationship between adherence and drug resistance correlates with increased adherence.

Socio-demographic factors have generally been found to have little predictive value in relation to adherence behavior (Eldred et al, 1998; Wise, 1996). Several studies, however, have found that certain socio-demographic factors (higher income, literacy, male gender, older age, and white race) do correlate with higher levels of adherence (Chesney et al, 2000; Gifford, et al, 2000; Kleeberger et al, 2001).

A number of treatment-related characteristics have been found to have a big impact on adherence behavior. These characteristics include medication-related side-effects which is noted to have a negative impact on adherence behavior. The complexity of treatment is another factor that has also been found to impact on adherence. Besides, the number, type and frequency of medication dosages; perceived fit of treatment into daily routine food restrictions, adverse events and complexity of schedule and perceptions of https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

HIV and HAART are also reported as important factors that can affect adherence (Gallant & Block, 1998, Altice et al, 2001; Freeman, Rodriguez, & French 1996; Kleeberger et al, 2001; Gifford et al, 2000),

There is little research that examines factors related to adherence in individuals who demonstrate high levels of adherence. Malcolm, Ng, Rosen and Stone (2003) compared subjects with excellent adherence (defined by the authors as taking medication consistently more than 90% of the time) to subjects with suboptimal adherence (defined as taking medication consistently less than 75% of the time). Their study, based on tenets of the Health Belief Model, used semi-structured interviews to examine attitudes and beliefs. In their study, a total of forty-four HIV sero-positive individuals currently taking HAART were surveyed.

Results of this study are consistent with findings of previous research in the area of adherence. They suggest beliefs about medication efficacy and the importance of adherence, patient-provider that relationships, social support, active substance abuse and depression differ between individuals with excellent adherence and those with sub-optimal adherence levels. A major shortcoming of the study was that it did not address strategies employed by those individuals with high levels of adherence to overcome identified barriers to excellent adherence.

Two other recent studies also used qualitative methodology to examine the experiences of individuals reporting high levels of HIV medication adherence. Gray (2006) used individual interviews in her grounded theory study of an ethnically diverse sample of 11 persons living with HIV. The purpose of her https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

study was to understand the process of becoming adherent from the participant s perspective. Lewis, Colbert, Erland & Meyers (2006) used semi-structured interviews to describe the adherence-related behaviors and attitudes of a sample of 13 mostly white, low income and unemployed men living with HIV.

In the latter study, the adherence behaviors of persons determined to be 100% adherent to antiretroviral medication was carried out. Results obtained suggest that the high levels of adherence were achieved principally because the subjects had realistic expectations, were practical in their approach and believed that the medicines prescribed for them were efficacious (Lewis, Colbert, Erland & Meyers2006).

The issue of adherence with medication is even more complex with HIV patients, as compared to other chronically ill patients, since it is not uncommon for patients to receive as many as 30 or more tablets per day. These complex medication regimens require that patients remember which tablet to take at what time and with food, which may be very difficult for many patients living with HIV (Muma, Ross, Parcel, & Pollard, 1995). The complexity of adherence to medication is also evident by the multiplicity of reasons behind it, which can be psychosocial factors, complex dosing schedules and instructions, etho-cultural concerns, or substance abuse. Suboptimal treatment can lead to drug failure and facilitate selection of one or more resistance mutations; once the selection begins, it is difficult or impossible to stop resistance, even with suboptimal treatment. Such

resistance could create new strains of the virus, creating a dangerous public health situation and decreasing the success of available HAART.

An important issue in the prediction of adherence is the presence of social support or satisfaction with social support. Coping has been examined frequently in the HIV adherence literature. Studies demonstrate that patients with a better adaptive coping, internal coping, problem-focused coping, and active-behavioral coping are associated with higher levels of adherence. On the other hand, avoidant coping styles are associated with non-adherence. Similar to traditional approaches to improving general medication adherence, interventions aimed at improving HARRT adherence among persons living with HIV have relied on information and instruction (e. g., disease education, medication, and dosing clarification), reducing barriers to compliance (e. g., goal setting and the examination of disease and medication-related beliefs), compliance reminders (e. g., memory aids and timers), and behavior modification (Epstein & Cluss, 1982; Hayes, Taylor, & Sackett, 1976; Ostrow, 1998).

Despite the variety of interventions aimed at improving adherence to HAART, many have proven to be only moderately effective. With medical and psychological advances of HAART, patients diagnosed with this disease are often left devastated and emotionally overwhelmed. Finding ways to cope with the diagnosis and make lifestyle changes are important aspects of care Chammas (1999) and Heinrich (2003) reported that hope is an important internal resource for helping individuals living with HIV to experience increased well-being and to survive with HIV. Cousins (1989) and Dufault and

Martocchio (1985) have also hypothesized that hope can facilitate healthier choices, while hopelessness has been connected with more destructive choices. Therefore, facilitating hope appears to be an important therapeutic goal in working with HIV positive individuals.

The positive role of hope in human life, in health and illness, is widely recognized and is significant in nursing. The meaning of hope to humans has been described my many philosophers, theologians, psychologists, and nursing researchers (Day, 1991; Eriksson, 1989; Fromm, 1968; Marcel, 1962; Nores, 1992; Ross, 1994). Research from many different disciplines suggests that hope and despair are closely interwoven with health and illness. Hope is considered an important coping strategy in the critical stages of human life (Obayuwana & Carter, 1982; Miller, 1983; Krause, 1993). In nursing science, many writers stressed the importance of hope on the part of the family of the sick person (Hickey, 1990; Koller, 1991).

In a study by Nikkonen (1993), people taking care of a dying relative at home also drew attention to the positive impacts of hope. The role of hope in helping individuals and their relatives has also been explored in many other disciplines (Mayeroff, 1971; Menniger, 1987; Staats, 1991). Here too, people at the receiving end have confirmed that hope plays a positive role in the healing process (Petet et al., 1991). Eriksson (1988) and Watson (1985, 1988) stressed the contributory role of hope in the nursing process.

Nursing research data provide some very vivid descriptions of hope that are rich in detail. Hope in nursing is described as a unique personal experience (Owen, 1984) and human capacity (Miller & Powers, 1988). Hope has been https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

defined as a subjective state that can influence realities yet to come. Once barriers are identified, nurses can improve adherence by developing interventions.

CHAPTER 3: RESEARCH METHODS AND DESIGN

Introduction

This chapter will begin with a recapitulation of the study's purpose statement. This will then be followed by the hypotheses and a detailed summary of the nature of study design proposed. Thereafter the setting and the subjects of the study will be described before an outlay of the inclusion and exclusion criteria is offered. Details of the recruitment procedure, power analysis and pre-test procedure are subsequently described.

the stratified simple sampling technique is selected as the preferred sampling method. The two variables to be assessed – hope and adherence to HIV medication- are fully explained in the section that follows. Next, the measurement tools, principally the Herth Hope Index and the Brief Medication Questionnaire are described in detail. Aspects of their usage, validity and reliability are enumerated in a broad manner. Subsequent sections focus on the techniques to be used in analysis of data and protection of the participants' privacy, identity, and human rights.

Statement of purpose

The purpose of this correlation study is to explore the relationship between hope and adherence to HAART medication in HIV patients. By examining the

adherence behaviours of patients who report adherence, it may be possible to discern whether there is a relationship between hope and medication among these individuals. Additionally, the nature and extent of such a relationship, if present, will be determined through this study. Strategies seen as supporting successful adherence behaviour might be shared with individuals currently having difficulties with medication adherence. Hence, the main purpose of this study will be to determine whether hope has an effect on medication adherence in HIV patients.

Hypotheses

Alternative Hypothesis

There is a relationship between hope and adherence to medication in HIV patients

Null hypothesis

There is no relationship between hope and adherence to medication in HIV patients

Type of design

This study will be a two group post-test only randomized quantitative correlation study. Correlational studies are designed so as to help ascertain if there is an existing relationship between two or more specified and quantifiable variables. The extent of the relationship between the variables is expressed as a coefficient of correlation. However, correlation is not taken as

being expressly indicative of a cause-effect association between the variables. This is more so because of confounding factors.

No. of groups and no. of times you will measure each group

Two groups will be specified in the study – the high adherence and low adherence groups as determined by the BMQ scale. HHI will be used to measure each of the groups once

Setting

The study will take place in the Veteran Administration Medical Center's HIV Clinic, located in North East United States. In this clinic, HIV patients receive all care related to their disease process. A staff nurse practitioner is the expert advisor for this study.

On average, a total number of (please specify) patients are seen daily in this hospital. In 2007 a total of (please specify) patients were diagnosed with HIV in this facility. The total number of inpatients with HIV/AIDS in 2007 was estimated at (please specify) 78% of the inpatients were adults and could speak, read and understand English.

Subjects

Subjects for this study will be HIV positive patients who meet the following criteria

Inclusion criteria

The following were used to determine eligibility for the study

- 1. HIV sero-positive, status known for at least 6 months,
- 2. May be un-employed or employed,
- 3. 18 years of age or older
- 4. Currently taking anti-retroviral medications
- 5. Perceived (per self-report) being able to complete adherent to the HAART regimen
- 6. Speaks, reads, and understands English
- 7. Agrees to be in the study

Exclusion criteria

- 1. Patients will be excluded from this research if they are deemed by the hospital authorities to be too sick to participate
- 2. Patients who are likely to be distressed with the study will also be excluded

Recruitment

Recruitment into the pre-test will be carried out for a period of two weeks and will be done as described in the following paragraphs. The records of the HIV inpatients at the hospital will be scrutinized in order to identify the patients who meet the inclusion criteria. This will be done after the necessary permission has been obtained from the hospital authorities. For the main study, the recruitment will take one month and subjects to be approached will be randomly selected using the hospital's records as detailed in the 'Sampling' section.

Identified patients will then be approached by the lead researcher who will introduce himself. Patients will be approached at a time when they are most https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

likely to be relaxing. The researcher will then introduce the study, explicitly stating the purpose, aims and objectives as well as the process of the study. The survey instruments will also be introduced to the patients. The researcher will explain that completion of the questionnaires will take a maximum of twenty minutes.

The patients will also be informed that their identity, privacy and rights will be protected. They will also be informed that they will be free to quit the study at any time they deem appropriate should they consent to participate. Other information as relating to protection of participants' identity, human rights and privacy as described in chapter 3 will be availed to them. For the main study, participants will be required to fill out the demographic survey.

Those who will agree to take part in the study will be given a pencil together with a cardboard file containing a cover letter. The latter will contain in details all the important aspects of the study including the aims, objectives, purpose statement and methods. Contained in the letter also will be the survey instruments. A clause stating that by completing the questionnaires inside the folder, the person was indicating consent to participate in the study will be inserted in the letter just before the survey instruments.

Participants will also be given the opportunity to ask questions should they wish to do so. Once the questionnaires are filled appropriately, the researcher will pick the complete file and thank the participant. No contact will be made with the participants again after this.

Power analysis

As High (2000) asserts, power is "the probability that a statistical significance test will reject the null hypothesis for a specified value of an alternative hypothesis." Stated differently, it is the capacity of any given test to identify an outcome which in fact is present. Power analysis is hinged on the appraisal of five key aspects. These include the significance level, effect size, the sample size, the power to identify an outcome, and the disparity in the response variable. Power analysis is thereby utilized to compute the sample size using the values of the other four aspects. The tool assesses whether there is enough power to warrant the study. The desired power in this study is . 80

Significance level

This represents the chance that a Type 1 error will occur. Stated differently, it represents the chance that a non-existent relationship may be ascertained. For this study, alpha =. 05 will be used. The researcher wants to be 95% sure that the null hypothesis is true (Polit, 1996).

Effect size

The effect size describes the magnitude of the outcome which the investigator needs to identify. Stated differently, the effect size is the difference or the spread of the score values around the means of the test groups. The independent t-test, one way Analysis of Variance or ANOVA and regression analysis are the three ways that are used to determine the effect size (Trochim 2008).

High (2000) asserts that the effect size and the capacity to identify it are inversely related. As such, it is easier to identify the effect size in instances where the effect is less significant. Conversely, it is more difficult to identify the effect size in instances where the effect is larger.

In this study, the effect size will be computed using the independent t-test. The following scale developed by Cohen (1988) will be used to interpret the outcome;

< 0.1 = trivial effect

- -0.3 = small effect
- - 0. 5 = moderate effect

> 0.5 = large difference effect

To carry out the power analysis prior to the study, an estimate of 0. 5 will be used. As MEERA (2008) opine, this value is usually used because it signifies a moderate to large variation.

Sample size

Lesser variances are observed with larger sample size. Thus, larger sample sizes are associated with the capacity to identify significant differences (High, 2000).

Procedure for selecting sample size

The sample size will be calculated based on the standard error as applied in normal curve tests. The formula, Sample size = s = s*z/T) ² as defined by Garson (2007) will be used to calculate the sample size. In this formula,

s represents the standard error of the variable which has the biggest variance. This will be ascertained through a pre-test carried out prior to the main study

z=1.96 at the significance level of . 05. This figure represents the number of standard units which match up with the preferred ratio of cases.

T is the permissible variation in the sample

Pre-test

A pre-test study will be carried out prior to the main study. Respondents in this pre-test will be derived from a convenience sample of HIV patients selected according to the main study's inclusion criteria. Both HHI and BMQ will be used as measurement tools in this mini study. The purpose of this pre-test is manifold. First, it will enable the researcher to determine the standard error described in the preceding section hence be able to compute an appropriate sample size for the main study. Secondly, the pre-test will enable the researcher assess the response rate and thereby put in place effective measures that would lead to reduction in non-response. Thirdly, the pre-test will be of utmost importance as it will help the researcher find out any incongruities in the survey instruments and refine them accordingly so that the main study proceeds on without any hitches.

Sampling

Sampling frame

The sampling frame will consist of the hospital register listing all in-patients diagnosed with HIV/AIDS at the Veteran Administration Medical Centre's HIV Clinic located in North East United States

Sampling method

The stratified simple random sampling method will be used to pick respondents for this study. This sampling method involves the random selection of respondents from each stratum of the accessible population using a simple number generator (Garson, 2008). This method is preferred because of several reasons. First, studies indicate that religion and education play a key role in influencing the outcomes of HHI scores. As Puchalski (2004) reports, higher HHI scores are reported for highly educated people and those who regularly attend worship. Thus, use of this sampling method will ensure that all the important sub-populations are adequately represented. Stratification will be done according to education, spirituality and disease stage. The latter category will comprise of those who are terminally ill with full blown AIDS and patients who do not have the full blown disease.

Dependent and Independent Variables

Independent variable

Hope

The theoretical definition of hope is "the belief that a positive outcome lies ahead" (Health link, n. d.). The operational definition of hope in this study will be a total score of between 24 and 48 in the HHI tool. Within this range, a score of between 24 and 31 inclusive will be used to denote 'hopeful', a score of between 32 and 39 inclusive to denote 'very hopeful' and a score of 40-48 to denote 'very very hopeful'.

At the other end, a HHI score of between 0 and 23 inclusive will be used to define hopelessness.

Dependent variable

Adherence

The following will be used as the theoretical definition of adherence.

Adherence (medication compliance) is defined as taking medications as prescribed by treating physician(s) without missing or in any way altering the dosage (HRSA, 2005; Thomson PDR, 2003). Herein acceptable adherence is considered as taking medication at least 95% as prescribed. The operational definition of adherence in this study will be a score of 9. 5 or more in the BMQ scale. Subjects with BMQ scores of less than 9. 5 will be classified as 'not adherent'.

Table 1: Table of Independent and dependent variables and the tools used to measure them

Measurement Tools

1. The Herth Hope Index (HHI)

The HHI is a 3-dimensional assessment tool used to collect information about patients' optimism. The three dimensions assayed are interconnectedness, mortality and the future, and anticipation and positive preparedness. These three dimensions constitute the tool's subscales. Developed by Dr. Kaye Herth in 1990, the HHI has 12 items each of which has a score of between 1 and 4 to give a total possible range of 12 to 48. The items are aggregated into the three dimensions with each dimension having a total of 4 items. Patients are ranked on a 1-4 Likert scale based on their responses to the items (Puchalski, 2004). This study will focus on both the total scores as well as the individual scores of the subscales.

Reliability and Validity of the HHI

Reproducibility and internal consistency are the two most vital parameters linked to reliability. As such, measurement tools are said to be reliable if and only if they can broadly satisfy these two parameters. In a measure of the tool's reliability, Herth (1990) determined the Cronbach's alpha to be 0. 88. Cronbach's alpha is a popular technique used to assess the internal consistency of items in a scale. It assays the degree of correlation between responses. Even though opinion is not unanimous on the cut-off level, values of 0. 70 and higher are regarded as acceptable measures of reliability.

Various aspects of validity among them content reliability, construct related and criterion validity was also evaluated. Results obtained indicated a negative correlation between hope scores and depression. Conversely, a positive correlation between hope and self-esteem was found. Hope scores were only affected to a large extent by education and religion. It is also

reported that the fear of death has a negative correlation (p0. 001) with hope scores and a positive correlation with hopelessness (p0. 05)

In other studies, (Herth 1992) finds the HHI to have an alpha coefficient of . 97. In the same study, a test-retest reliability coefficient of . 91 is reported. Chen (2003 p. 62) similarly reports a Cronbach's alpha of . 88 for HHI in a study of pain and hope in patients with cancer.

The Burden of the HHI

As Puchalski (2004) asserts, the burden of the HHI measurement tool is yet to be ascertained. As such, there is no conclusive indication of the time and cost it takes to administer the tool, its effect on the respondent, response rates and presence of omissions.

The reading level of HHI

HHI has a Flesch reading level of 74. 8% and a Flesch-Kincaid Grade level of 4. 5. The Flesch-Kincaid Grade level is a measure of the education level that is required for the reader to be able to comprehend the writings with ease. The Flesch-Kincaid Grade level has a scale which ranges from 0 to 12. Ease of reading is indicated by a lower score while a larger score is indicative of a difficult to read document. As can be seen, the HHI tool can be easily understood by the respondents. On the other hand, the Flesch reading level is a quantitative measure of how easy or difficult it is to read a document. The scores range from 0 to 100. Documents that are easy to read have high scores while those that are hard to read have lower scores. From the

foregoing, it can be seen that respondents will have an easy time reading through the HHI instrument (Microsoft, 2008)

2. The Brief Medication Questionnaire (BMQ)

The BMQ is a self-report tool that was developed in order to monitor patient adherence and identify impediments to adherence. The tool is widely used to detect patients who require help with their medicines. BMQ is also used to evaluate the worries of patients as well as appraise new plans. It consists of a Regimen Screen, a Recall Screen and a Belief Screen. The three different screens make up the tool's subscales. The Regimen Screen has 5 items which inquires how patients took medication in the past week. The Recall Screen has 2 items and assesses the ability of patients to remember. The Belief Screen examines the impacts and inconveniences associated with the drugs being taken (Svarstad, Chewning, Sleath and Claesson, 1999). This study will seek to get both the total scores and the scores of the subscales.

Reading level of BMQ

BMQ has a Flesch reading level of 88. 5% and a Flesch-Kincaid Grade level of 2. 9. As can be seen therefore, it can be seen that the BMQ is easily understood and highly legible.

Reliability and validity of BMQ

Numerous studies have been carried out to determine the validity of the BMQ tool. Svarstad, Chewning, Sleath and Claesson (1999) assessed the validity of BMQ using the Medication Events Monitoring System (MEMS). A sample size of 20 was evaluated. A sensitivity of 80-100% was reported for https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-sample/

the "repeat" non-adherence for both the Regimen and Belief Screens. The Recall Screen was found to have a sensitivity of 90%. The conclusion was that BMQ is the most potent tool for the detection and analysis of adherence problems.

Godin, Gagne and Naccache (2003) studied non-adherence to ART medication among HIV patients in Canada using the BMQ. The aim of this prospective longitudinal study was to validate the BMQ instrument. The sample size was 256 and the benchmark for validity assessment was the CD4 cell level. Results indicate that BMQ has adequate validity, with a sensitivity of 71%, specificity of 72%, an odds ratio of 6. 15 and a correct classification of 72%. Other studies have similarly asserted the validity of BMQ as a tool for measuring non-adherence (Deschamps et al, 2008; Muñoz-Moreno et al, 2007; Diabat et al, 2007 and Simoni et al, 2006).

1. Demographic tool

The demographic tool used in this study will evaluate the following variables: gender, age sex, educational background, present financial background, employment status, current losses, ethnic origin, living arrangement, and time since diagnosis, role responsibilities, daily activities, and physical energy (Appendix F).

Reliability and Validity

Internal consistency reliability

Internal consistency reliability will be conducted using the Cronbach's alpha test

Criterion-related validity

Changes in the patients' viral load counts will be used to ensure the validity of the results obtained. In this regard, assessment of the respondents' CD4 count will be done and comparison of the counts with self reported adherence scores made. The rationale is that lower CD4 counts will be associated with high BMQ scores and high CD4 counts with low BMQ scores. Wide variations between the self-adherence BMQ scores and the CD4 counts will be deemed to be invalid.

Data analysis

Data analysis will be done using both descriptive and inferential statistics.

Descriptive statistics will be used to depict the elemental characteristics of the data obtained. In this regard, univariate analysis will be carried out and measures of central tendency, dispersion and distribution depicted appropriately. Concerning the measures of central tendency, the mean, mode, and median of the score values will be computed. Standard deviation will be used to assess the dispersion of the score values. Frequency distribution will be used to describe the spread of the ranges of the score values (Trochim, 2008).

Inferential statistics will be carried out so as to examine correlation between the defined variables. The General Linear Model, specifically the simple t-test will be used to analyze the data. As Trochim (2007) asserts, this technique is suitable for the two-group posttest only randomized experiment. The formula given by displayed below will be used to compute the relationship

Hope and hiv medication and adherence es... - Paper Example

Page 35

Source Trochim (2008)

Data management

Data c ollection: procedure protocol

Here, data gathered will be logged in, verified for accuracy, entered into the computer, transformed, and a database structure incorporating the different computations built. Information gathered will be logged in using standard computerized software (Ms Access) prior to analysis. Original data will be preserved using standard record-keeping procedures

Data Coding

Categories of responses will be coded using an emergent approach described by Haney, Russell, Guklek & Fierros (1998), which consists of several steps. First, using a single transcript, the investigator and his dissertation advisor will conduct independent reviews of the transcript to condense responses into classifications to which a coding scheme could be applied. Second, they will discuss their findings, establish agreement between their initial coding schemes, and create a consolidated coding scheme.

Third, the consolidated coding scheme will be used to independently code a second transcript. Fourth, the results of the independent coding of the second transcript will be compared to determine the reliability of the coding. Two forms of reliability are desired: 1) stability or the same coder getting the same results each time, and 2) reproducibility (inter-rater reliability) or

coding schemes that produce the same results from different people (Stemler, 2001).

Inter-rater reliability

For inter-rater reliability a 95% agreement is suggested. Haney et al. (1998) suggest using a Cohen's Kappa (which equals 1 if coding agreement is perfect) of . 8 or greater to determine inter-rater reliability rather than a percentage (number of cases coded the same divided by the total number of cases coded) as there is a degree of agreement that will occur between raters due to chance which is not accounted for in the percentage approach. If an acceptable level of agreement will not be achieved the independent coders repeat the process. Once agreement has been reached the coding scheme can be used with the remaining transcripts. Analytical technique for this study is bivariate. If the missing data will make a noticeable difference in the analysis, the participant will be excluded from the study. Potential sources of error in measurement are human, random, processing data, and variations in coder's interpretation of data

Data Entry

Entry of data into the computer will be by typing. Data entered thus will then be checked for accuracy using the double entry procedure. In this method, special software enables data to be keyed in a second time and subsequently checks each second entry against the first entry. The program identifies disparities and alerts the user so that correct entries can be made.

In this way, the obtained data is cleaned and it is made certain that the numbers in the computer match the information collection.

Trochim (2006) explains that database programmes are vital tools in data management as they provide greater flexibility in the analysis of data than statistical programmes. Ms Access will, as such, be used to store the data with a different structure from the one used in logging in. A codebook will be developed in line with good research practices (Trochim, 2006). This code book will describe the data and specify how it can be retrieved. It will contain the variable name, description, and format. Additionally, the code book will indicate the method of data collection used, the date on which the information was gathered, as well as the respondents in the study. The variable location in the database and notes will—also be contained in the code book.

Data transformation, also called data conversion, denotes the practice of altering data from their raw form into a format which better supports its analysis (Zikmund, 2003 p. 480). This will be conducted to ensure usability of the data in the analysis.

Reliability and validity for each measure

As stated previously, assessment of the respondents' CD4 counts will form the basis for ensuring the validity of the BMQ measurement tool. The alpha coefficient will be used to assess reliability in both the HHI and the BMQ instruments. Reliability of the demographic data will be ensured by cross-checking against available hospital records.

Potential sources of error

Potential sources of error include typographical mistakes, misunderstood questions and inappropriately circled responses. Other potential sources of error include measurement errors and processing errors. Measurement errors are said to result from either or all of the following: the questionnaire, the technique used to gather data, the interviewer and or the respondent (OMB, 2001). Possible measurement errors in this study include the inability of the respondents to understand the survey items and thus give a misunderstood answer, inability to correctly remember information, and inability to accurately render the response. Possible processing errors in this study include recording errors where incorrect data is recorded, imputation errors, and errors attributable to entry of data and editing.

Handling of missing data

To ensure that all the information obtained is complete and accurate, immediate verification of the data will be carried out. The objective will be to seek for clarification from the sample sources in the event of errors. In verification of the data, attention will be paid on the legibility and completeness of the responses given. Accordingly, emphasis will be put on whether all important questions have been answered and all pertinent background information such as time, place, and date included. Illegible and incomplete responses will be rectified through clarification from the sample sources. These sources will also be contacted to help correct data where some important questions were not answered and/or where omission of relevant background information was noticed.

Protection of human subjects

The following will be carried out in order to protect participants' rights. The researcher will be open and honest with the participants about all the aspects of the study. In this regard, all the participants will be informed about the aims and objectives of the study, the requirements for participation, anonymity in relation to the outcomes of the study, reporting of information related to them and any probable risks of participation on them. Secondly, participants will be allowed to exit from the study any time they may wish to do so.

Protection of participants' identity

To protect participants' identity, each participant will be assigned a unique subject number. This subject number will be used at all times in place of the participant's name

Protection of participants' privacy

Behi & Nolan 1995 explain that ensuring privacy for the study participants means that no one else but the researcher will know the source of the data obtained in the study (cited in Speziale & Carpenter, 2003). Protection of participants' identity will be ensured through the following steps

- 1. Confidentiality agreements will be signed by all individuals assisting with the research
- 2. Permission to use direct quotes will be sought from the participants (Speziale Carpenter, 2003)

- 3. Revealing data such as written demographic data and taped interviews will be securely stored in a safe filing cabinet whose key will only be in the possession of the researcher. These will be destroyed by incarceration or shredding two months after the research is completed. Electronic data will be archived in a database with a strong password known to the researcher only. The hard disk will be formatted two months after the completion of the study.
- 4. Publications will not identify the participants. Where revealing data such as photos need to be published, informed consent will be sought and obtained from the participants. Additionally, publications will report group and not individual data.
- 5. Certificates of confidentiality will be sought from the National Institutes of Health. As Acta Bioethica (2004) explains, these certificates protect the anonymity of the data obtained in a study by giving the researchers and institutions immunity from being forced to provide this data. When obtained, the participants in this study will be made aware of this.
- 6. Consent will be stored in secure filing cabinets separate form the survey data and demographic information

Protection of human rights

sample/

Protection of human rights will be ensured by seeking and obtaining the Medical Centre and the university institutional review board's approval for the study. Informed consent will be sought from the patients. This will be obtained by elaborating the aims and procedures of this research to the patients. Informed consents are obtained when the participant arrived at the https://assignbuster.com/hope-and-hiv-medication-and-adherence-essay-

research session. Each participant will be asked to give standard written consent verifying willingness to participate in the research study. The Case Western Reserve University Consent form will be used. This consent will attest to the informed and voluntary nature of their participation as well as their knowledge about the study's aim. Each participant will be as assured that he could terminate participation at any time. Data will be collected at the hospital bedside once the patients have been admitted and at the convenience of the patients.

References

Altice, F. L., Mostashari, F., & Friedland, G. H. (2001). Trust and the acceptance of and

adherence to antiretroviral therapy. *Journal of acquired immune deficiency* syndromes, 28 1) 47-58.

Andreo, C., Bouhnik, A. D., Soletti, J., Bertholon, D. R., Moatti, J. P., Rossert, H., &

Spire, B. (2001). Non-compliance in HIV-infected patients, supported by a community association. *Sante, 13* (3) 249-62. Arnsten, J. H., Demas, P. A., Bangsberg, D. R., Hecht, F. M., Charlebois, E. D., Chesney, M. A., & Moss A. R. (2001).

Comparing objective methods of adherence assessment: Electronic medication

monitoring and unannounced pill count. *AIDS and Behavior, 5,* 275-281. Bartlett,

Behi , R & Nolan , M. 1995 . Ethical issues in research. British Journal of Nursing 4

(12): 712-716.

Chammas, G. Y. (1999). Hope, functional status, and quality of life in hospitalized

patients with HIV and AIDS. *Dissertation Abstracts International, 60* (3-B), 1027. Chesney, M. A. (2000). 'Factors affecting adherence to antiretroviral therapy.' *Clinical*

Infectious Diseases, 30, s171-176. Chesney, M. A. (2003). Adherence to HAART

regimen. AIDS Patient Care and STDs, 17, (4), 169-177. Chesney, M. A.,

Chesney, M. A., Ickovics, J., Hecht, F. M., Skipia, G., & Ragkin, J. (1999).

Adherence: A

necessity for successful HIV combination therapy. AIDS, 13 (sA3), s271-278.

Cohen, J. (1988). Statistical power analysis for the behavioural sciences (2nd ed.). New

Jersey: Lawrence Erlbaum.

Cousins, N. (1989). *Head first: The biology of hope* . New York: Dutton. Day, J. (1991).

Hope: A philosophical inquiry (Vol. 51). Helsinki: Philosophical Society of Finland.

Daar, E. S., Cohen, C., Remien, R., Sherer, R., & Smith, K. (2003). Improving adherence

to antiretroviral therapy. AIDS Reader, 13, 81-82, 85-86, 88-90

Deeks, S. G. (1998). Practical issues regarding the use of antiretroviral therapy

for HIV infection. Western Journal of Medicine, 168 (2), 133-139.

Diabat, S.??, Alary, M. & . Koffi, C. K AIDS. 2007, Vol. 21, No. 13: 1799

Dufault, K., & Herth K (1992) Abbreviated instrument to measure hope: development

and psychometric evaluation. <u>Journal of Advanced Nursing</u>. 17, 10, 1251-1259.

Farzadegan, H., Grant, R. W., Gourevitch, M. N.; Chang, C. J., et al. (2001).

Antiretroviral therapy adherence and viral suppression in drug users: comparison

of self-report and electronic monitoring. *Clinical infectious diseases: an official*

publication of the Infectious Diseases Society of America, 33(8) 1417-23.

Feudtner, C. (2005). Hope and the prospects of healing at the end of

Life. The Journal of Alternative and Complementary Medicine, 11 (), 23-30.

Freeman, R. C., Rodriguez, G. M., & French, J. F. (1996). Compliance with AZT

treatment regimen of HIV-seropositive injection drug users: a neglected issue.

AIDS Education and Prevention. 8 (1), 58-71.

Fromm, E. (1968) *The revolution of hope.* New York: Harper & Row . Frick, P. A., Gal,

P., Lane P. W., & Sewell, P. C.(1998). Antiretroviral medication compliance in patients with AIDS. *AIDS Patient Care and STDs.* 12 6 463-470.

Friedland, G. H., & Williams, A. (1999). Attaining higher goals in HIV treatment: The

central importance of adherence . AIDS, 13 (s1), s61-s72. Hope and HIV Medication Adherence 44

Gallant, J., & Block, D. (1998). Adherence to antiretroviral regimens in HIV-infected

patients: results of a survey among physicians and patients . Journal of the International association of Physicians for AIDS Care, 4, 32-35.

Gao, X., & Nau, D. P. (2000). Congruence of three self-report measures of medication

adherence among HIV patients. *The Annals of Pharmacotherapy, 34(10),* 1117-

Gao, X., Nau, D. P., Rosenbluth, S. A., Scott, V., & Woodward, C.(2000). The relationship of disease severity, health beliefs and medication adherence among

HIV patients . AIDS Care, 12(4), 387-398 .

Gibbs, A. (1997). Focus groups. Social Research Update: Focus Groups