

Volume 1

**Adherence to combination therapies in people with
HIV/AIDS**

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ABSTRACT

Combination therapies have changed the lives of many individuals living with HIV and AIDS. High levels of adherence to the drugs are advocated for the therapies to be effective. At the same time non-adherence to the drugs has been linked to viral resistance and disease outcome. The practical and emotional demands of HIV treatment regimens are emerging as a major problem for adherence. Ethnic background has also been associated with low rates of adherence. In particular, it has been reported that black users of the drugs are more likely to be non-adherent.

The Health Belief Model has been widely used in studies that have used theory driven methodologies to address adherence issues. According to this model adherence can be predicted from individuals' beliefs about the severity of HIV/AIDS, their susceptibility to it and the costs and benefits of taking the medication. However, fewer studies have used the revised Health Belief Model which includes two further concepts: Cues-to-action and self-efficacy. The present study aimed to use the revised Health Belief Model to identify contributing factors to non-adherence with combination drugs and to further explore the factors that could account for the low rates of adherence among different ethnic groups.

This was a cross sectional study that utilised both quantitative and qualitative methods to address its research aims. The study was carried out at a north London district that serves a culturally diverse community. Fifty six participants were asked

to complete a Health Belief Model questionnaire and an Adherence to Combination Drugs questionnaire. A focus group of seven black African participants was also conducted to explore in greater depth the difficulties of taking combination drugs in this population. Relationships between health beliefs and adherence to combination drugs were explored using regression analyses and correlation coefficients, while content analysis was carried out on data collected from the focus groups.

The findings of the present study serve to support the relevance of the Health Belief Model in examining adherence difficulties. In particular, it was shown that beliefs about the difficulties and benefits of the drugs alongside the use of cues to remind individuals to take their drugs were strong predictors of adherence to combination therapies. Moreover, the findings from the focus group suggested that beliefs regarding HIV/AIDS and the drugs need to be considered within the wider socio-economic context of the individuals receiving these therapies. The findings were further discussed in relation to the areas that they identified as important in improving the likelihood that medication will be appropriately utilised by individuals in combination therapies.

CHAPTER ONE: INTRODUCTION

Non-adherence to drug treatments is widely recognised as a major problem for medical and other health-related disciplines. Serious problems can be created by low rates of adherence. The treatments will often be less effective and while in certain cases this may carry little personal risk, non-adherence with some treatments can be life-threatening as well as being expensive. This is particularly true in the case of HIV (Human Immunodeficiency Virus) treatments.

There is growing evidence that adherence to the new class of protease inhibitor drugs for the treatment of HIV infection may have a beneficial effect on health and survival. Findings suggest that aggressive treatment which reduces viral load to the lowest possible level holds out the greatest hope of extending life expectancy (American Study of Combination Therapy, as cited in Alcorn, 1996). At the same time however, non-adherence has been linked not only to viral resistance but also to variable quality of life and disease outcome (Ickovics and Meisler, 1997). Moreover, ethnic background has been associated with low rates of adherence although variables contributing to ethnic differences in adherence have not as yet been explored systematically.

Most of the studies that have employed theory driven methodologies to address adherence issues, have primarily used the Health Belief Model (HBM; Rosenstock 1974). The HBM suggests that adherence can be predicted from concepts such as perceived severity of HIV and AIDS, perceived susceptibility to it and costs and benefits to taking the medication. However, fewer studies have systematically used

the revised HBM which includes two further concepts: cues-to-action and self-efficacy. Rosenstock, Strecher and Becker (1988) argued that both of those concepts are important additions to the model as they can increase its explanatory power.

The present study aims to explore the relationship between the revised HBM and measures of adherence to combination therapies in people with HIV and AIDS and explore the factors that may contribute to the ethnic difference in adherence levels. A review of the HIV illness and the issues related to adherence to medical treatments will be initially presented. Subsequently, a review of the available combination therapies prescribed today and the issues related to their adherence will be outlined followed by a discussion of the factors that have been shown to affect adherence to combination treatments. Moreover, a brief review of the psychological models used to understand adherence difficulties will be included, with particular emphasis on the description of the Health Belief Model. Finally, the aims and hypotheses of the present study will be outlined.

1.1 THE ILLNESS

Human Immunodeficiency Virus is responsible for the cause of Acquired Immune Deficiency Syndrome (AIDS). It is called human because there are other related viruses of this sort which affect animals. This virus has the ability to infect the cells that fight infection and produce antibodies, such as the T-lymphocyte blood cells and to multiply itself within these cells and damage them. This failure in the body's defence or immune system is called "immunodeficiency". When someone has AIDS

their body's normal defence mechanisms against infections, diseases and tumors are greatly reduced. AIDS develops, on average, 10 to 11 years after HIV infection occurs (British Brain and Spine Foundation, 1998).

1.1.1 Demographic information

Human immunodeficiency virus (HIV) infection is found throughout the world. It is estimated that more than 10 million people are currently infected with the virus, men women and children included (British Brain and Spine Foundation, 1998). In Europe the majority of people affected are homosexual men and intravenous drug users. In Africa most are heterosexual.

The present study is carried out at Enfield and Haringey, a district that serves a culturally diverse community. Of the 602 people living with HIV in this district 47% of this population are from ethnic minority communities with the majority 40% being black Africans (Atkins and Badcock, 1999). An analysis of 300 patients attending the district hospital had showed that 60% of the new patients presented to the hospital in 1997 and 1998 were African (Forde, 1999). Enfield and Haringey have devised a local HIV action policy for African communities that has influenced the development of similar policies in other health authorities. In fact, over the last year the Enfield and Haringey Health Authority (EHHA) has been funded by the Department of Health to co-ordinate a range of HIV health promotion initiatives targeted at the African Communities across England.

1.2 ADHERENCE TO MEDICAL TREATMENT

1.2.1 Definitional issues

Adherence is a relatively new term that has been used over the last few years to replace the older term of compliance. The most frequently cited definition of compliance has been provided by Hayes (1979), who described it as “the extent to which a person’s behavior (in terms of taking medication, following diets, or executing lifestyle changes) coincides with medical or health advice” (Epstein and Cluss, 1982, p951). Inherent to this definition is the assumption that medical advice is good and the patient has to passively accept and follow the medical advice as the standard (Myers and Midence, 1998). It also follows that unsuccessful treatment means a non-compliant patient who failed to follow the clinician’s advice, placing thus the blame for the lack of health improvement largely on the patient (Varni and Wallander, 1984).

In contrast, the term adherence implies a more collaborative relationship between the patient and the doctor. The patient has an active role to play in the planning and implementation of the therapeutic regimens. The conceptual shift from compliance to adherence has been seen as the first step towards empowering the patient to make informed choices regarding the ways the patient copes with illness and utilises particular treatments (Myers and Midence, 1998). With this definition in mind, non-adherence has become a multi-factor issue. To date research has identified factors affecting adherence as characteristics of (a) the individual, (b) the treatment regimen,

(c) the patient-provider relationship, (d) the clinical setting and (e) the disease (Ickovics and Meisler, 1997).

1.2.2 Assessing levels of adherence

Failure to adhere with medication taking may include omissions of doses, taking medication for the wrong reason, errors in dosage or timing or sequence and discontinuing therapy before the end of the recommended course (Haggerty and Roghmann, 1972). Therefore, assessing adherence is a very complex task.

A number of different ways of measuring adherence have been developed most of which focus on the accurate assessment of the amount of medication ingested by the patient. Indirect methods such as patient self-report, pill count or volume measure and physician estimates of compliance are generally not expensive or time-consuming but are subject to inaccuracy and/or falsification. More objective methods, including blood and urine assays may be more accurate but are often expensive, unavailable, or simply unreliable in long-term assessment (Epstein and Cluss, 1982).

1.2.3 Adherence in ethnic minorities

The phenomenon of non-adherence occurs in patients of all social classes, ethnic groups and health care delivery systems (Hays and DiMatteo, 1987) and regardless of symptom severity or medical assessment of disease severity (Hayes, 1979). However, it has been argued that despite this ubiquity of non-adherence, it is

nevertheless worth considering whether there are any categories of patients whose adherence rates are different from those of other groups, or for whom the sources of non-adherence vary. Specific interest in this area has been shown by those wishing to understand adherence issues and encourage greater adherence from those with low rates so that such patients may better benefit from what the health system has to offer (Joshi, 1998).

The Health of the Nation Government strategy document (Department of Health, 1993) set targets for the improvement of health and pointed to the need to ensure that all members of the community share in the improvements. Ethnic minority groups are mentioned as being likely to have specific needs and it is argued that it is worth considering whether members of minority groups are likely to have particular difficulties in accessing services and /or following advice. Difficulties would arise if, for example, patients lacked knowledge of services were unfamiliar with either the English language or with the rules and rituals of the medical encounter in the UK, or if medical advice clashed with culturally specific beliefs and practices. It has been argued that health behaviour can only be understood with reference to other beliefs and behaviours and to the wider socio-economic and political context. (Joshi, 1998). These are all therefore important issues to be considered when studying non-adherence among individuals from difference cultural and ethnic backgrounds

1.3 COMBINATION THERAPIES

Rapid progress is being made in designing drugs to combat HIV infection. As a result to date a number of drugs exist that are prescribed in combinations to control HIV infection.

Combination therapy is the term used to describe using three or more drugs to treat HIV. It is also called triple therapy or HAART (Highly Active Anti-Retroviral Therapy). It involves using drugs which work in different ways and which target the virus at more than one point of its life-cycle (Aids Treatment Project, 1999).

The drugs currently available aim to reduce the multiplication of the viruses, or its growth and in this way may delay the appearance of immunodeficiency and the onset of AIDS. Three main groups of drugs are currently used:

Group 1, *Nucleoside Analogues*: drugs that block the action of a special enzyme in the virus which allow it to use the human genetic material to multiply itself within the cells of the body. This group includes drugs such as Zidovudine (AZT), Lamivudine (3TC), Zeret (d4T), Zalcitabine (ddC).

Group 2, *Non Nucleoside Reverse Transcriptase Inhibitors*: a different group of drugs which also work against the enzyme that allow HIV to reproduce and infect new cells. These drugs work best for people who have not used other anti-HIV drugs. In this group there are drugs such as Delavirdine and Loviride

Group 3, *Protease Inhibitors*: drugs that inhibit or impair the action of a different viral enzyme which is essential for viral maturation, i.e. that prevent the virus from “growing” and reaching its full potential as a disease-causing organism. Drugs in this category are Indinavir, Ritonavir and Saquinavir (National Aids Manual, 1998).

Clinical trials of combination therapies have generated great optimism among clinicians in the field. According to clinical trials of Ritonavir and Saquinavir, adding protease inhibitors to existing drug regimens extends life and reduces disease progression. For example Alcorn (1996) reported on two studies that have demonstrated the effectiveness of these drugs. In the first study, a follow-up of patients with AIDS randomised to receive Ritonavir or placebo in addition to their existing drug regimen showed that after 230 days of treatment, patients receiving Ritonavir had 50% lower risk of progressing to a further opportunistic infection or death compared with the placebo group. In the second study, the results of a two year follow-up of patients on Saquinavir and ddC showed that use of this combination resulted in a similar reduction of risk when compared with either drug alone.

Today, at a national level over two thirds of all people with HIV using an NHS hospital for their care are taking combination therapy and 85% of these are on combination of three or more drugs (Atkins and Badcock 1999). These drugs have changed the lives of many people living with HIV and AIDS and have offered hope to many more (Anderson and Weatherburn, 1998a).

1.3.1 Side effects

Like all medicines, anti-HIV drugs can cause a number of side-effects. Different drugs cause different side-effects, including mild ones that may wear off such as nausea, diarrhoea, rash or tiredness and more serious ones such as peripheral neuropathy and lipodystrophy-a term used to refer to changes in fat distribution. Most side-effects occur during the first eight weeks after the start of a new drug. For side effects such as nausea, diarrhea and headaches other medicines are usually prescribed to reduce their effects. For the more serious ones, changing to another drug combination is frequently the way by which such side-effects are dealt with (Aids Treatment Project, 1999)

1.3.2 Monitoring amount of HIV in blood

There are primarily two ways by which the amount of HIV in blood can be detected, namely by a CD4 count and a viral load test.

The CD4 count is the measurement of the number of CD4 cells in a cubic millimetre of blood. The most important information that a CD4 count can give is the overall trend of ones immune system's health- whether it is declining or improving. A CD4 count between 500 and 200 indicates that some damage to the immune system has occurred while a CD4 count below 200 means that one is at risk from serious infections such as pneumonia or other life threatening infections (National Aids Manual, 1999).

Viral load tests estimate the number of HIV particles in a sample of blood and the result of the test is described as the number of “copies” of HIV per millilitre. The more HIV in ones blood, the faster the CD4 cells are likely to disappear and the greater the risk of developing symptoms or further illness within the years to follow (National Aids Manual, 1999).

Taken together both CD4 and viral load provide valuable information to predict the likelihood of developing AIDS in the short to medium term.

1.3.3 Resistance to combination drugs

HIV reproduces very quickly producing new generations of viruses that differ slightly from one another. These changes to the structure of the virus over time can improve its ability to reproduce despite high levels of anti-HIV drugs being present. Viruses which are able to reproduce despite taking the drugs are said to be resistant to those drugs (National Aids Manual, 1999).

Combining several drugs delays resistance, because together they have a much more powerful effect on the virus than a single drug on its own. Moreover, it is very important that anti-HIV drugs are taken as prescribed to minimize resistance. This means taking every dose, spacing the doses correctly and following any guidance about the kinds of food that need to be taken with. Taking too little of a particular drug, for example by missing or delaying doses will lower the amount of the drug which is active in the body and so reduce the drug combination’s attack on HIV. Virus which was suppressed will then begin to reproduce faster, increasing the risk

of resistance. Missing even a few doses a month may be enough to cause the treatment to fail (National Aids Manual, 1999).

1.4 ADHERENCE TO COMBINATION THERAPIES

Although medication adherence has been the subject of numerous studies over the last 30 years for conditions such as diabetes, tuberculosis, arthritis and severe and persistent mental health disorders, there is still little known about the degree of adherence necessary to effect a therapeutic outcome for known therapies. (Rabkin and Chesney, 1998)

In most studies successful adherence is defined as more than 80% of doses. However, most estimates fall in the range of 30-60% with somewhat lower rates for prophylactic medications and these estimates do not take into account timing between doses or dietary restrictions.

Researchers investigating adherence to combination drugs have used the 80% or better level of adherence in their studies. For example Rabkin and Chesney (1998) reviewed the result of five studies which found AZT adherence rate to range from 42% using a time frame of the past month to 67% in the time frame of the past week. Rabkin and Chesney went on to explain that these rates are consistent with findings reported in the general medical literature.

However, unlike other conditions, clinical trials have shown that with HIV treatments resistance to combination drugs can develop when patients miss a few days or even a few doses of medication and thus the 80% convention may not be applicable to antiretroviral therapy (Rabkin and Chesney, 1998).

The National Aids Manual (1999) notes that one of the keys to the success of anti-HIV drugs and opportunistic infection treatments and prophylaxis, is taking the drugs that one is prescribed at the right times, in the right amounts, and in the right way. This is because missing doses, taking the right dose, or taking a drug in such a way that you absorb too little of it may lead to the more rapid development of resistance to the drug and you may stop benefiting from it. All the makers of protease inhibitors have found that when people who were responding well started to lose the benefits, the most common explanation was that they were missing or reducing doses, or stopping one or more of the drugs (National Aids Manual, 1999).

In light of the above, adherence to combination drugs needs be defined and measured in terms of :

- (a). taking all the drugs prescribed
- (b). taking the correct dose of each drug
- (c). taking each drug at the correct time
- (d). following the instructions about whether to take it with food or on an empty stomach

There are no studies today that have used the above definition to study adherence to combination therapies. It is however with this definition in mind that the present research was conducted.

1.4.1 Factors affecting adherence to treatment

Taking combination therapies however is not always easy. The practical and emotional demands of HIV treatment regimens are emerging as a major problem for adherence. So, although patient adherence may be a top priority for health professionals, for the person with HIV, concerns such as controlling symptoms, normalizing social interactions, preventing medical crises and enjoying a quality of life may take precedence. All these concerns can in turn effect levels of adherence to combination therapies and undermine their effectiveness.

A number of studies have tried to identify factors specific to the treatment regimens. Outcome literature in chronic disorders has found that the more complex the treatment regimen and the longer it will have to be followed the more likely it is not to be adhered to (Leventhal and Cameron, 1987). Similarly regimens that require lifestyle changes (e.g. diet, smoking or alcohol cessation) are less likely to be adhered to, being more demanding on the patient's change of behaviour (Rissman and Rissman, 1987). In terms of HIV/AIDS factors including complex treatment, lifestyle demands and side effects such as diabetes, diarrhoea and nausea may affect adherence to combination treatments.

The presence of mental health problems has also been identified as a reliable indicator of likely adherence difficulties. Depression and psychological stress has been shown to predict non-adherence in HIV patients (Singh, Squier, Sivek, Wagener, Hong Nguyen and Yu, 1996). In a study of HIV patients, 43% of the depressed as compared to 56% of the non-depressed patients had used antiretroviral therapy (Burack, Barret, Stall, Chesney, Ekstrand and Coates, 1993). In the same study depression was associated with a greater decline in CD4 counts and a trend towards accelerated mortality, which the authors attributed to both the effect of depression on the immune system and its effect on adherence. Additionally, depressive behaviour has been associated with self-neglect, apathy and forgetfulness, all of which may result in non-adherence (Anderson and Kirk, 1982).

Ethnic or cultural background was also shown to be associated with low rates of adherence. Singh et al (1996), found that adherence was lower in black patients independent of social support, employment and depression. Anderson and Weatherburn (1998b) for example reported that Black Africans were more likely to be non-adherent to combination therapy than any other ethnic group, although their study involved a small number of African participants (9% of their sample) something that seems to be an endemic problem in researching African communities. However, variables contributing to racial differences in adherence have not been defined. It has been hypothesised that differences in health beliefs and conflicting socio-cultural concepts of illness and its treatment could account for the reported low rates of non-adherence in clients for ethnic minorities.

Studies such as the above present a pragmatic attempt to identify the causes of non-adherent behaviour. The philosophical starting point of these studies seems to be the notion that non-adherence is a trait characteristic which may be linked to certain socio-demographic or dispositional features of the patient (Horne, 1998). They have been however criticised for being atheoretical in their approach and failing to acknowledge the substantial theoretical literature that is currently available and it is to these theoretical frameworks that we now turn to.

1.5 A THEORETICAL OVERVIEW OF MODELS FOR UNDERSTANDING ADHERENCE TO MEDICAL TREATMENTS

Developments in health and social psychology have contributed several theoretical frameworks for the study of health-related behaviours. These frameworks have been used in various degrees in the study of treatment adherence and they are frequently referred to as the “social cognition models” since they all tend to share the assumption that attitudes and beliefs are major determinants of behaviour (Horne and Wienman, 1998). These models include the Health Belief Model (HBM; Rosenstock 1974), the theory of Reasoned Action (TRA; Fishbein & Azjen, 1975), the Theory of Planned Behaviour (TPB; Azjen 1985) and the Social Cognitive Theory (e.g Bandura, 1977, 1986).

All these models will be briefly reviewed. However, particular attention will be placed on discussing the Health Belief Model since it has provided the theoretical framework for the present study and as such its main premises will be presented last

followed by research evidence into its use for understanding adherence to combination therapies.

1.5.1 The Theory of Reasoned Action (TRA) and the Theory of Planned Behaviour (TPB)

The central tenets of the TRA propose that behavior is largely guided by intentions. Intentions are in turn determined by attitudes towards performing the behavior and by subjective norms concerning the behaviour. It is suggested that attitudes derive from the individual's beliefs about the likely consequences of a particular behaviour and their evaluation of those consequences. Subjective norms refer to beliefs regarding others' views about the behaviour and the motivation to support these views (Ajzen and Fishbein, 1980).

TPB was proposed by Azjen (1988) as an extension of the TRA and included an additional concept that of "perceived behaviour control" a concept that describes the extent to which an individual feels that behaving in a certain way is within their control. This is dependent on control beliefs such as perception of both internal resources such as skills or information and external resources such as perceived barriers (Connor and Sparks, 1996). This concept "perceived behaviour control" is considered to be similar to that of self-efficacy, which will be described in the following section (Horne and Weinman, 1998).

So, according to these models, given equally strong intentions, individuals who are confident of their ability to perform a behavior and perceive few obstacles are more

likely to actually perform the behaviour (Horne and Weinman, 1998). However, TRA and TPB were developed from research investigating relationships between attitudes and behaviour outside the health arena. Both models have therefore been criticised for not including an assessment of health threat, an important determinant of health-related behaviour, as is present in other models (Conner and Norman, 1998).

1.5.2 The Social Cognitive Model

This model has been primarily evolved out of the work of Bandura (Bandura, 1977, 1986, 1997). It proposes that the likelihood of a behaviour occurring depends on an individuals' perceived self-efficacy, the belief that a given behaviour is or is not within one's control and outcome expectations. Two types of outcome expectancies have been described: situation outcome and action-outcomes. Situation outcomes expectancies represent beliefs about what consequences will occur without interfering personal action, so for example susceptibility to a health threat represents one such situation-outcomes expectancy. Action-outcome expectancy is the belief that a given behaviour will or will not lead to a given outcome (Conner and Norman, 1998).

So, according to this model individuals are more likely to consider different actions to minimise unhealthy behaviours when they perceive themselves susceptible to health risks and at the same time feel confident to carry out the actions considered. This model serves to underline the importance of self efficacy as an powerful factor and predictor of health-related behaviour, although it has also been criticised for its

lack of consideration of social influences on behaviour, such are to be found in the TPB (Conner and Norman, 1998).

1.5.3 The Health Belief Model (HBM)

The HBM incorporates many of the tenets of the above models. The model was initially developed to explain the peoples' failure to participate in programs to prevent or to detect disease (Rosenstock, Strecher and Becker, 1994). It has since been widely used to explain a range of health related behaviours adherence being just one of them.

The original HBM

The HBM assumes that individuals will take action to deal with ill-health conditions if they regard themselves as susceptible to the condition and if they believe the health condition to have potentially serious consequences. Moreover, individuals will take action if they believe that a course of action available to them would be beneficial in reducing either their susceptibility to or the severity of the condition; and if they believe that the anticipated barriers (costs) to taking the action are outweighed by its benefits (Rosenstock et al, 1994).

The above assumptions have been traditionally described under four constructs (see figure 1.1):

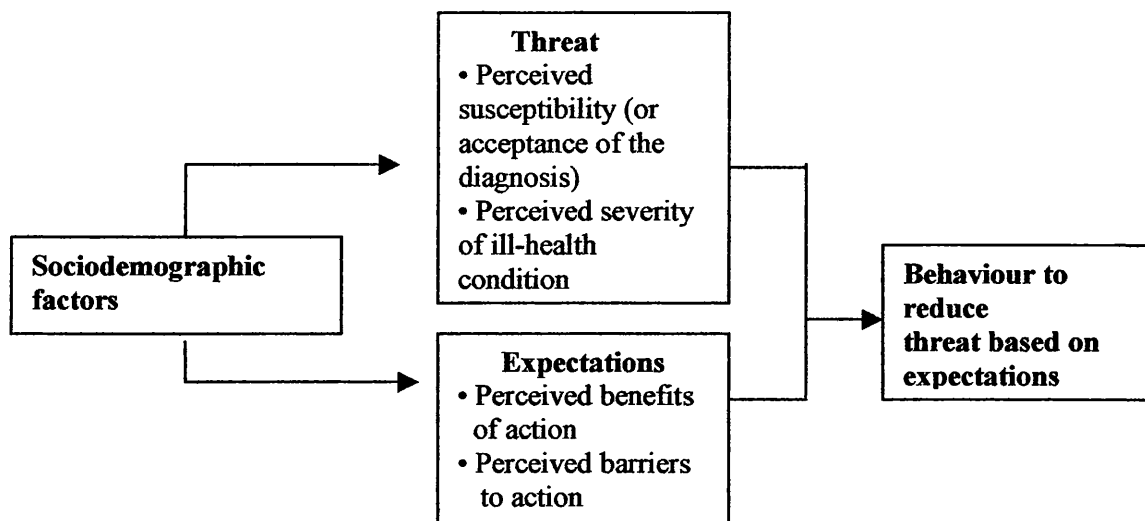


Figure 1.1: Schematic diagram of the components of the original Health Belief Model (Rosenstock, Strecher and Becker, 1994).

- Perceived susceptibility, that is ones' subjective perception of the risk of contracting a health condition.
- Perceived severity, that is ones' feelings concerning the seriousness of contracting an illness or not treating it and this include evaluations of medical, clinical and social consequences e.g death, pain, effects of condition on work, social relations and so forth.

Together these variables are believed to determine the likelihood of the individual following a health related action, although their effect is modified by individual differences in demographic variables, social pressure and personality (Conner and Norman, 1998)

The other two constructs are:

- Perceived benefits, that is beliefs regarding the effectiveness of various actions in reducing and managing the effects of the illness on health and finally,
- Perceived barriers, that is beliefs regarding the potential costs in undertaking a specified health related action e.g. costs of medication, unpleasant side-effects, inconvenient health regimens and so forth.

Thus while the combined levels of susceptibility and severity provide the energy and force to undertake a specified health-related action, a cost-benefit analysis of the alternative behaviours provides a preferred path of action (Rosenstock, 1974).

The revised HBM

Over the years, several revisions have been made to the original model, to include the concepts of cues-to-action and self-efficacy (Rosenstock et al, 1994), as presented in figure 1.2.

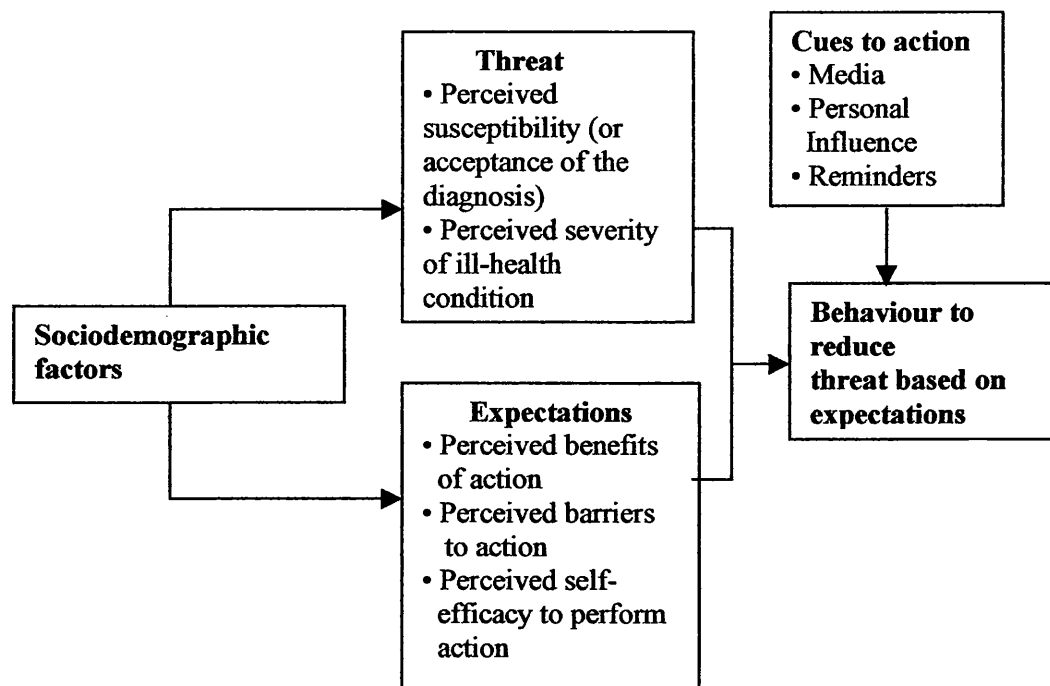


Figure 1.2: Schematic diagram of the components of the revised Health Belief Model (Rosenstock, Strecher and Becker, 1994).

Cues-to-action: The concept of cues which trigger action was discussed in various early formulations of the HBM but it has not been systematically studied. This is unfortunate, since it has been reported that anecdotal evidence supports the importance of brief, though salient cues that stimulate a decision to act (Rosenstock et al, 1994). So in HBM terms, if the perceived AIDS threat is high and perceived benefits of a certain AIDS preventative behaviour outweigh the perceived barriers of the behaviour, a cue-to-action can prompt or trigger an individual to adopt and maintain this behaviour. Similarly however, to perceived barriers and benefits, it is important to determine what cues-to-action exist as well as their relative efficacy in influencing AIDS-preventive behaviours.

A diverse range of triggers including individual perceptions of symptoms, social influence and health education campaigns can act as cues-to-action. For example,

physicians advice or recommendations have been found to be successful cues-to-action in the context of smoking cessation (Wienberger, Green, and Mandin, 1981). Patient encounters with the health care system, including consistency in procedures, ensuring privacy, providing information and sensitivity to the emotional state of the individual and communication between patient and physician have been shown to be associated with levels of adherence to treatments (Weishut, 1996). Although this research does not appear to be explicitly theory driven, it draws on an implicit theory that the quality of the patient's interaction with the health professional is of prime importance (Horne, 1998).

Postcard reminders have also been successful as cues-to-action (Larson, Bergman and Heidrich, 1982). Ogionwo (1973) on the other hand found that a radio, film and poster campaign was successful in attempts to prevent cholera.

Studies into the factors affecting adherence in HIV patients have not as yet systematically explored such important cues-to-action as the above. It would be particularly useful for example, to investigate the effects of reminders such as pill boxes, pill timers e.t.c. on adherence with combination therapies.

Self- efficacy: Self-efficacy is defined as “the conviction that one can successfully execute the behaviour required to produce the outcomes” (Bandura, 1977) and is also encountered as a prominent construct of the social cognitive model discussed above.

The original focus of the original HBM was on circumscribed preventative actions such as a screening test, which involves simple behaviours for individuals to

perform. Thus, it is likely that most participants had adequate self-efficacy and that dimension of the model was not even recognised. However, the problems involved in changing lifelong habits concerning eating, drinking, exercising, smoking, and sexual practices are far more difficult to surmount than are those for accepting a one-time immunisation or a screening test. It requires a good deal of confidence that one can in fact, alter life-styles before successful change is possible and this is particularly true to taking combination therapies for HIV. Thus, for behaviour change to succeed, people must feel threatened by their current behavioral patterns and believe that change of a specific kind will be beneficial, but they must also feel themselves competent (self-efficacious) to implement that change (Rosenstock et al, 1994).

Most studies today using the HBM have failed to acknowledge the importance of this concept in preventing non-adherence to combination therapies.

Rosenstock et al (1988) argued that self-efficacy and cues-to-action must be added to the HBM in order to increase its explanatory power. As Strecher and Rosenstock (1997) added more work is needed to specify and measure factors that need to be added to the model to increase its predictive power.

The HBM as an interactive model

Strecher and Rosenstock (1997) argued that the vast majority of HBM-related research analyse the constructs of the model separately. They went on to explain that analyses that essentially throw all health belief constructs into a multiple regression model do not test the HBM as a whole model. They also noted that

researchers generally fail to examine how individuals with various combinations of health beliefs were more or less likely to change health-related behaviour. They went on to suggest the following hypothesis that researchers may wish to consider:

- Perceived threat is a sequential function of perceived severity and perceived susceptibility. A heightened state of severity is required before perceived susceptibility becomes a powerful predictor behavior outcome.
- Perceived benefits and barriers will be stronger predictors of behavior change when perceived treat is high than when it is low. Under conditions of low perceived threat, benefits of and barriers to, engaging in health-related behaviour will not be salient.
- Cues-to-action will have a greater influence on behaviour in situations where perceived threat is great.

The above hypothesis can be represented as follows (figure 1.3),

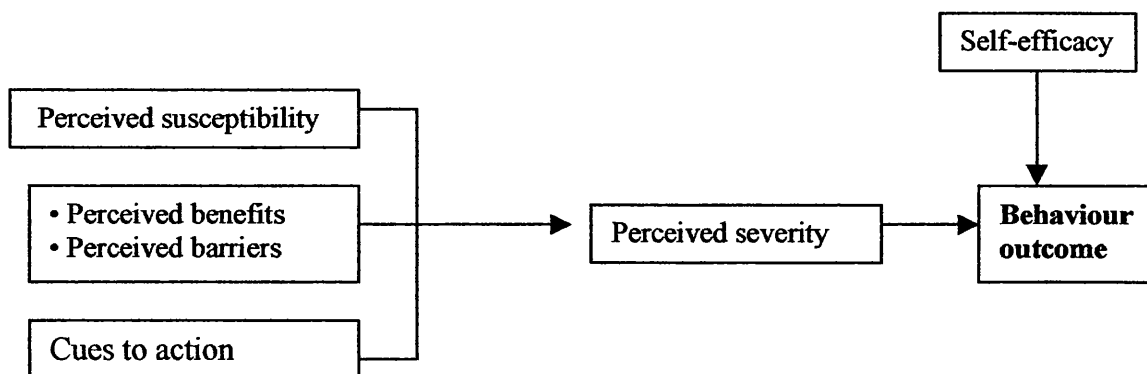


Figure 1.3: Schematic representation of perceived severity as a moderating factor.

where severity is thought to act as a moderating factor between susceptibility, perceived costs, benefits and cues-to-action and health-related behaviours. To date there are no studies into adherence with combination therapies that have examined the above hypotheses and tested the HBM as an interactive model.

Socio-demographic factors

The authors of the HBM have not neglected to acknowledge the effect of a wide range of other variables that could potentially effect health- related behaviours. It has been argued that diverse demographic and socio-psychological variables may affect the individual's perceptions and thus indirectly influence behaviour (Rosenstock et al, 1994). For example, it has been suggested that educational attainment has an indirect effect on behaviour by influencing the perception of susceptibility, severity, benefits and barriers (Rosenstock et al, 1994). Therefore, the influence of such factors needs to be borne in mind when employing the HBM for understanding and predicting health-related behaviours.

1.5.4 The social cognition models: critique and conclusions

The description of the models above serve to highlight the considerable overlap in the variables that they describe. So for example, intentions, perceptions of health risks, outcome expectations and beliefs about ability to take action, have all played a role in describing the cognitive processes that underlie health-related behaviours as described by these models. In turn, the identification of these processes has provided

researchers and clinicians with the basis to develop effective interventions designed to alter the cognitions underlying unhealthy behaviours.

While these models have been popular and influential in health education and prevention efforts they have also been subject to increasing criticism on conceptual grounds. The main criticism appear to address the proposed causal relationships between cognitions and actions, the focus on an individual, rational decision maker, and the exclusion of interactional processes and other non-cognitive variables. For example, it has been argued that the decision to use a condom is likely to be not only a function of cognitions, but also of emotional reactions and a complex interaction between the individuals involved. Therefore social cognition models are unlikely to provide considerable predictive power in such situations (Conner and Norman, 1998).

Despite the above criticism the popularity of social cognition models still prevail. As Conner and Norman (1998) went on to explain, these models provide a clear theoretical background to research, guiding the selection of variables to measure, the procedure for developing reliable and valid measures and how these variables are related in order to predict health behaviours and outcomes. It is with these advantages in mind that researchers continue to use the social cognition models in the study of a variety of health-related behaviours and in particular adherence to medical treatment.

1.5.5 The Health Belief Model and the present study

The present study employed the HBM as its theoretical model on the basis of its popularity and wide use in health-related research. Moreover, the constructs incorporated in the HBM show great overlap with the concepts in the other cognitive models described above covering thus an extensive range of concepts that could predict health-related behaviours. Finally, the choice of the HBM in the current study was also determined by the fact that most studies into adherence to combination therapies have used this model. Although these studies may differ in their operationalisation of the HBM constructs, nevertheless they permit the comparison of results regarding the usefulness of the constructs in predicting adherence to anti-HIV treatments. These studies are described in the following section.

1.5.6 Adherence to anti-HIV treatments and the Health Belief Model

The HBM has received greater research attention and has been applied to a broader range of health behaviours than any other social cognitive model. These include preventive health behaviours, clinic use and physician visits.

In terms of adherence to recommended medical regimens, a meta analysis of 51 studies of the HBM with adults conducted by Harrison, Mullen and Green (1992), found significant positive relationships between perceptions of severity, susceptibility, benefits and barriers and risk reduction behaviours such as adherence to medication regimens. That is, adherence is found to be greater when the person

perceives the need for treatment, believes the treatment will be helpful and understands the purpose of the medications (Rabkin & Chesney 1998).

Fewer studies have specifically examined associations between health beliefs and medication taking in HIV positive individuals. Samet, Libman, Steger, Dhawan, Chen, Shevitz, Dewees-Dunk, Levenson, Kufe and Craven (1992) reported on their findings regarding adherence to AZT – a drug prescribed on its own before combination therapies became available- which was measured using serum Zidovudine levels. It was shown that 33% of their 83 patients were non-adherent and were taking less than 80% of the prescribed dosage. Characteristics associated with greater compliance were a strong belief of AZT for prolonging life and use of a medication timer as a cue or reminder. The study did not examine the relationship between self-efficacy and adherence to AZT.

Morse, Simon, Coburn, Hyslop, Greenspan and Balson (1991) examined the relationship between health beliefs and adherence with AZT among subjects involved in an experimental protocol. Adherence was measured by a nurse's judgement. Single-item health belief variables were examined for their associations to adherence. Their results suggested that poor compliers were more likely than those judged as compliant to report barriers to taking medication because of the inconvenience of the regimen. However, the study did not provide an indication of the relationship between beliefs about perceived threat of HIV and adherence to medication.

Catt, Stygall and Catalan (1995) conducted a more comprehensive study of the relationship between the HBM and adherence with AZT in HIV positive individuals. 28 participants were asked to complete self-reported questionnaires on the core four health beliefs constructs. Items were also included to access the construct of cues to action. Participants were divided into those that accepted AZT treatment and those that declined it. No differences were found in relationship to perceived severity of HIV and perceived vulnerability to disease progression between the acceptors and the decliners. However those that had accepted the treatment had a greater need to see that the beneficial side of therapy outweighed the difficulties of the therapy and claimed that they had been told by their doctor to initiate treatment. Decliners on the other hand justified their action by interpreting the costs to outweigh the benefits of the treatment and claimed that their doctor had not told them to initiate early treatment. They also appeared to be waiting for bodily symptoms to cue their actions. However, the study examined differences in beliefs among those that chose to receive the treatment and those that did not, and as such it did not address difficulties with adherence among those that accepted the treatment.

Muma, Ross, Parcel and Pollard (1995) also utilised the HBM in exploring the relationship between health beliefs and adherence to AZT as measured by the combination of dosage and regimen and by blood samples. A self-rated HBM questionnaire was administered to 52 individuals with HIV. It was reported that participants who had problems taking AZT or were sceptical about the value of it were less compliant and thus the results were in line with the HBM which holds that the balance between barriers and benefits of a health related behaviour are significant determinants of outcome. However, perceived severity of disease, which

the HBM also holds as a predictor, was not significant. The authors went on to suggest that this finding may support the argument that the concept of severity may have low utility when applied to severe illnesses such as HIV. In addition the study's findings indicated that compliance varied significantly by ethnicity, with African-Americans showing a lower level of compliance. The authors went on to propose that further investigation into this finding should examine other co-factors, such as socioeconomic status, language and culture before any conclusions are drawn.

Finally, Aversa and Kimberlin (1996) reported on their findings of the relationships between health beliefs and adherence to combination drugs. Perceived severity, susceptibility, benefits/barriers, cues to action and locus of control were all included in the analyses. Ninety nine participants were grouped in terms of whether they had discontinued their treatment on their own initiative, altered their drug regimens on their own initiative or took their medication as prescribed. It was found that those that reported greater perceived barriers and less faith in the ability of the drugs to protect them from AIDS related illness were more likely to discontinue drug therapy. However, contrary to expectations a relationship was not found between the cues to action and medication. Although the study fails to report on the relationship between perceived severity and susceptibility and adherence to drugs, nevertheless their results are in support of previous research findings that indicate that adherence is tightly linked to beliefs about the quality of life effects of the anti-HIV drugs and to doubts about the effectiveness of antiretrovirals in prolonging life. It still remains however, for future studies to systematically explore the role of perceived severity of HIV and susceptibility to HIV as determinants of adherence to combination therapies.

1.6 THE PRESENT STUDY

The urgency by which combination therapies are developed and prescribed alongside the need for high levels of adherence to these treatments, has also brought about an urgency in understanding and predicting non-adherent behaviour. As Epstein and Cluss (1982) pointed out the effectiveness of treatments for a chronic disease depends on two factors: the efficacy of the treatment and the rate of adherence to the treatment.

Therefore, the study of adherence in HIV treatment has been viewed as important for improving the likelihood that medication will be appropriately utilised with the expectation of extending life and improving quality of life. The literature reviewed serves to underline on the one hand the complexities involved in adhering to combination therapies and on the other hand the wealth of primarily atheoretical research efforts to address those complexities. Most of these research efforts are generated by the feeling that a comprehensive understanding of factors underlying medication adherence is critical to developing health education and intervention programs for HIV patients (Durvasula, Golin and Stefaniak, 1998).

Moreover, taking into account the research findings relating ethnic background to different levels of adherence with medication, alongside the fact that the area from which this study is recruiting is a culturally diverse district, a population vulnerable to non-adherence to HIV treatment was indicated. Exploring the levels of adherence

in this population provides the opportunity to further explore and substantiate the differences reported in the literature.

1.6.1. The methodological framework of the present study

This study utilised both quantitative and qualitative methodologies to address its aims and hypotheses. It has been argued that researchers have traditionally seen quantitative and qualitative methods as operating within different paradigms (Todd, 1998). However, recently many writers have argued that this distinction is unproductive and unnecessary (Orford, 1995) and it has been recognised that a combination of both types of methods can be advantageous (Todd, 1998).

Rossmann and Wilson (1991) suggest a number of advantages of a mixed method approach. Triangulation is one such advantage as data collected through two different methods may enable confirmation or corroboration of each other. Combining methods may also allow the researchers to elaborate or develop analysis, providing richer detail.

The quantitative methods used in this study seemed appropriate to address our initial aims since it involves considering differences among participants in frequencies of particular behaviours and allows for comparisons with previous studies.

The qualitative methods used in this study were considered suitable to address the final aim of this study. Qualitative methods are considered suitable when researching individual processes, interpersonal relations and wider social processes (Charmaz,

1995). So, given the lack of research focusing on the experiences of black users of combination therapies, it seemed important to collect more detailed and contextual data that could capture the richness of black participants' experiences.

1.6.2 The aims of the present study

The present study was driven by two main aims:

- (a) to carry out a theory-based research investigating adherence to combination therapies using the HBM
- (b) to explore adherence differences among individuals from black communities.

We will now turn to consider the hypotheses of this study as related to each of these aims.

The first aim

The first aim of the present study is to test the revised HBM as applied to adherence to combination therapies. According to this version of the model, adherence to combination therapies could be predicted from the following constructs: Perceived severity of HIV; perceived susceptibility to HIV; perceived benefits and costs of taking combination drugs; perceived ability to take the drugs as prescribed (self-efficacy); and finally the use of reminders to assist the taking of the drugs as prescribed. The following hypothesis was therefore formed:

1. Participants who believe in the severity of HIV/AIDS and feel susceptible to the condition, believe that the benefits of the drug therapies outweigh their costs, feel confident to take their medication and utilise strategies to help them remember to take their drugs as prescribed, would be more likely to adhere to the combination therapies than those that do not share those beliefs.

Furthermore, following Rosenstock et al (1988) suggestions regarding improving the predictability of the HBM, the present study also aims to explore the extent that self-efficacy and cues to action are adding to the predictive power of the traditional version of the HBM, the hypothesis being that:

2. The revised model of the HBM will account for greater variability in adherence with combination drugs than the traditional HBM.

Moreover, the present study will also address the criticisms presented by the authors of the model, regarding the way that the HBM has been routinely statistically used. As Strecher and Rosenstock (1997) explained analyses that examine the HBM constructs individually and independently of each other do not test the HBM as a whole model. They emphasised the importance of understanding how combinations of HBM constructs, as opposed to individual constructs, can predict changes in health-related behaviour. Thus, in an attempt to address these criticisms and pave the path towards exploring the HBM as a combination of constructs rather than a collection of equally weighted variables operating simultaneously, the following hypothesis was formed:

3. Perceived severity to HIV/AIDS will moderate the effects of perceived susceptibility, perceived benefits, perceived barriers and cues-to-action on adherence measures to combination therapies.

The second aim

In light of findings indicating the need to consider whether there are categories of people that show different rates of adherence than other groups (Joshi, 1998), alongside findings that show black clients rates of adherence to combination therapies to be lower than other ethnic groups, the study aims to further explore the presence of similar findings in this study. The following questions were formed:

1. Do black participants show lower rates of adherence to combination therapies compare to the white participants in this study?
2. If there are differences between the black and white participants in terms of adherence levels, could these differences be explained in terms of differences in the participants'
 - (a) beliefs about the severity of HIV
 - (b) beliefs about their susceptibility to HIV
 - (c) beliefs about the benefits of the combination therapies
 - (d) beliefs about the costs of the combination therapies
 - (e) beliefs about their ability to take their medication as prescribed
 - (f) use of strategies to help them remember to take their medication as prescribed.

Furthermore, and in light of the fact that reasons to explain differences in the presence of low rates of adherence with combination drugs among ethnic groups have not as yet been systematically explored, the present study aims to ascertain the views and feelings of black participants regarding adherence to combination therapies by conducting a focus group to address the following questions:

3. How do black users of combination therapies understand adherence to the drugs?
4. What reasons do they give to explain the research findings that indicate low rates of adherence among black users of the therapies.

For ease of understanding and clarity, the quantitative and qualitative parts of the study are presented separately. The methods and results of the quantitative part are presented first followed by the methods and analysis of the qualitative part of the study. The findings of both parts are commented on in the Discussion section, the final chapter of the present study.

CHAPTER TWO: A QUANTITATIVE STUDY OF THE DETERMINANTS OF ADHERENCE TO COMBINATION THERAPIES: TESTING THE HEALTH BELIEF MODEL

2.1 OBJECTIVE

The objective of this part of the study was to investigate the relevance of the Health Belief Model in adherence to combination therapies for people with HIV and AIDS. The research hypotheses and questions of the present study were addressed by a cross sectional study. Quantitative data were collected via questionnaires and standardised measures of the constructs under investigation (see measures section). Ethical approval was granted by the Enfield and Haringey LREC (see Appendix 1).

2.2. METHODS

2.2.1 Participants and settings

Participants were recruited from the following places:

- the T1- HIV outpatient ward, at North Middlesex Hospital- patients attend the clinic for appointments, blood tests and collecting their medication.
- the FACTS (The Foundation for AIDS Counselling, Treatment and Support) drop-in and support services for people with HIV/AIDS, Crouch End.
- the Umoja drop-in centre for people from African communities in Enfield, where

African individuals can access information regarding HIV/AIDS and available treatments and meet socially fortnightly.

All the above places serve the multi-ethnic population of Enfield and Haringey district. Exclusion criteria were as follows:

- individuals who were not taking combination therapies
- individuals with insufficient command of the English language to complete the questionnaires

Demographic information is presented in the Results section.

2.2.2 Materials

Participants were asked to complete the following set of questionnaires:

Demographic data form: This form asked about the participants age, sex, ethnicity, educational level, sexuality, relationship status and current living circumstances. In light of the fact that participants were recruited from a multi-ethnic population, the form also asked participants to report whether English was their first language (Appendix 2).

The Health Belief Model Questionnaire (HBM): This was a self-report questionnaire designed by the author of this study. It was constructed to explore the participants' health beliefs about taking combination therapies.

The questionnaire was based on the Catt et al (1995) 30-item HBM scale, in the form of self-statements constructed to reflect beliefs associated with taking AZT (a drug widely prescribed to HIV patients before combination therapies were available). The Catt et al scale was designed to cover five areas of the HBM: perceived severity of HIV disease, perceived vulnerability to HIV disease, perceived benefits of AZT, perceived costs of AZT and cues to action (all these constructs have been defined and discussed at the Introduction to this study).

The Catt et al scale was adapted to reflect beliefs about combination drugs. Additional items were generated from the available research literature (presented in the Introduction) and in consultation with professionals in the field such as doctors, nurses, HIV counsellors and clinical psychologists. These additional items aimed to add to the measure of the different HBM constructs and provide a measure for the construct of self-efficacy (a construct also defined at the Introduction section) that was not included in the Catt et al study. Particular attention was placed in the wording of the items. Strecher and Rosenstock (1997) argued for the need to include a behavioral anchor when measuring perceived susceptibility. For example, a behaviorally anchored question for AIDS-preventative behaviour would ask “If you do not take combination therapy, how likely are you to develop opportunistic infections?” Ronis (1992) found strong evidence to support the importance of asking susceptibility questions that are conditional on action or inaction. Fifty five items were generated in total.

The next step in the construction of the questionnaire was to assess its validity. The procedure used by Champion (1984) to check the validity of a HBM questionnaire

regarding breast self-examination, was adopted. The 55 items were randomly presented to 7 judges all of whom were psychology lecturers, doctoral students and clinicians knowledgeable about the HBM. Only those items which at least 5 out of the 7 judges agreed represented the HBM constructs were retained. By this procedure the extent to which the items accurately and adequately reflect the content of the HBM component is checked (Sheeran and Abraham 1998). So for example, most judges agreed that items such as “I have the ability to take my medication even though it interferes with my social life” or “I am confident that I can overcome any difficulties I have with taking combination drugs” were representing the construct of self- efficacy while items such as “reading good reports about combination drugs has encouraged me to take them” or “I use pill boxes to remember when to take my medication” was agreed that represented cues to action. On the other hand items such as “whilst my body remains symptom free I should avoid taking combination drugs” were dropped from the questionnaire as some of the judges felt it represented the concept of perceived susceptibility to HIV while others felt it represented cues to action.

The end product was a 45-item HBM questionnaire. Items were rated on a five point Likert scale from “strongly agree” to “strongly disagree” (Appendix 3). Reliability analyses were also carried out to determine whether the questionnaire items accurately measure the constructs in question and they are reported at the Results Section.

The adherence to combination drugs questionnaire: This questionnaire consisted of 25 questions which aimed primarily to gather data on participants drug regimens. The questions were generated in consultation with clinicians in the field and from questionnaires such as the Positive Lives 1999 questionnaire (ID Research, 1999), a questionnaire that also explored individuals experiences of taking combination therapies. The adherence to combination drugs questionnaire also included questions that inquired about the participants relationship with their doctor, their knowledge of the way that combination therapies need to be taken and the strategies that they employ to help them remember to take their medication as prescribed. In addition there were questions regarding other kinds of therapies that participants may be having such as homeopathy, reflexology e.t.c. (Appendix 4). For the purposes of the present study only the questions inquiring about the participants drug regimens were used.

In the same questionnaire participants were asked to rate their level of adherence to their combination treatments (Appendix 4, question 18). Epstein and Cluss (1982) argued for the importance of determining the precise definition of adherence used by investigators that will allow for the appropriate measures of adherence to be designed.

Thus in operationalising adherence, the National Aids Manual (1999) definition -as described at the Introduction Section- was used. With this definition in mind, participants were asked to report how much of the time during the past week were able to:

- (a) take the correct dose of each drug
- (b) take the medication at the right time
- (c) follow instructions about whether to take drugs with food or an empty stomach
- (d) take the right dose of combination drugs, at the right time and in the right way.

All the above have been described as important for ensuring the success of combination treatments. Therefore, assessing differential adherence to the varying components of the combination drugs regimen is an important aspect of the overall adherence picture. Participants rated their adherence to the above items on a five point Likert scale from “all of the time” to “none of the time”. The time frame of one week was chosen as shorter reporting periods tend to be associated with more accurate recall (Catania, Gibson, Chitwood and Coates, 1990). Four measures of adherence were therefore included in this study.

Self-report methods of assessing adherence have been often criticized for giving an over-estimate of medication adherence ((Myers and Midene 1998). Despite the reported criticisms regarding the unreliability of self-reports, research today continues to rely on self-report methods as ethical and practical considerations limit the use of more direct assessment methods. As Epstein and Cluss (1982) argued the researcher or clinician interested in assessing adherence must choose a method considering both the practicality and the data regarding the validity of the chosen method.

Therefore along this lines, a number of studies have presented evidence in support of the use of self-report measures of adherence. For example, Kaplan and Simon(1990) maintained that patients can be very accurate in reporting the likelihood that they will adhere to treatment if they are asked simply and directly. Weinhardt et al (1998) concluded that “well-designed interviews and questionnaires can provide acceptable data when administered properly” (p174), and went on to make a number of recommendations for improving the quality of self-reports. These include: language that is easily understood; sensitivity to cultural issues of participants; establishing a working trust with participants e.g. giving assurance about confidentiality; sequencing the inquiry from least to most threatening questions. These recommendations were adhered to as far as was practicable.

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983): The HADS was developed as a screening device for detecting anxiety and depression in hospital patients. It is a 14-item self-report questionnaire consisting of two subscales, one for anxiety and one for depression. The items are rated on a four point scale (0-3) according to how they have been feeling over the past week. The authors suggest that for either subscale (anxiety or depression) a score of 7 or less represents “non-cases”, a score of 8-10 represents “bordeline cases” and a score of 11 or greater represents” definite cases”. The HADS excludes somatic items and is therefore, particular applicable with non-psychiatric hospital clinic populations (Zigmond & Snaith, 1983). Hermann (1997) reports the internal consistency of the anxiety scale to range from .80 to .93 and the depression scale to range from .80 to .90. The reliability of the scale for assessing severity of anxiety is $r = .75$ and for depression is $r = .70$ (Zigmond & Snaith, 1983).

2.2.3 Procedures

The procedure for recruitment of participants was developed in consultation with ward and drop-in centres staff. Following arrival at the ward reception or at the drop-in centre potential participants were approached and asked whether they were currently on combination therapies. Those that confirmed the use of combination drugs were subsequently offered written information about the study (Appendix 5). If they indicated an interest in participating, the nature of the research was further explained and written consent was obtained (Appendix 6). They were then given the study's questionnaires to complete whilst waiting for appointments or while spending time at the drop in centre. Participants especially those waiting to see their doctor were given the option of completing the questionnaires in a room off the main waiting area to maximise privacy. Questionnaires were self-administered and anonymous. They were either handed back to the researcher or alternatively if the researcher was not present and if the participants had no time to complete them during their stay at the centres, they were returned in the stamped-addressed envelope provided.

2.2.4 Data analysis

Once data were collected, participants responses were coded and statistical analyses were carried out using the Statistical Package for the Social Sciences (SPSS/PC+4.0).

Independent samples t-tests and chi-square tests were used to explore the effects of anxiety, depression and demographic variables on adherence measures while logistic regressions and correlations were employed to examine the effects of the HBM constructs on levels of adherence with combination therapies.

2.3 RESULTS

The results of this part of the study will be presented in two sections. The first section will include the descriptive exploration of the data collected in terms of a range of descriptive statistics such as percentages, means, and standard deviations. The second section will describe the reliability analyses that were carried out on the HBM questionnaire and the statistical analyses conducted to test the hypotheses of the present study.

2.3.1 DESCRIBING THE DATA COLLECTED

2.3.1.1 Response Rates

A total of 35 individuals on combination therapies were approached by the researcher and asked to participate in the study. Of those 5 refused to take part (2 black women, 1 black man, 2 white men), the most frequent reason given was insufficient command of the English language to complete the questionnaires or simply lack of interest in the study. This resulted in a response rate of 86%.

In addition, a total of 40 sets of questionnaires were handed out to individuals attending the drop-in centres we recruited from. Stamped addressed envelopes were provided so that completed questionnaires could be returned to the researcher. Of those, 25 sets of questionnaires were returned, resulting in a response rate of 63 %.

As a result, a final sample of 56 participants was acquired.

2.3.1.2 Demographic Details and reported levels of anxiety and depression

Participants ranged in age from 21 to 67 years. The mean age of participants was 40 years (SD=8.44). The gender and ethnic origin of the participants are shown in figure 2.1.

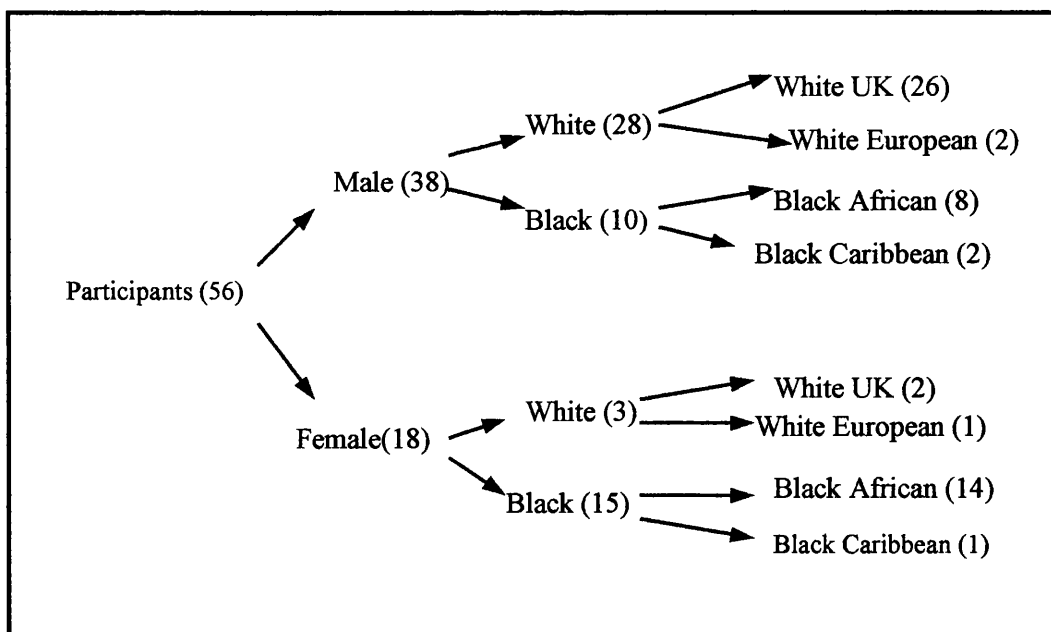


Figure 2.1: Breakdown of participants –brackets show the number of individuals in each category.

The majority of the participants were men (68%, n =38). 55% were white and 45% were black. In light of demographic information showing Haringey and Enfield to be a culturally diverse district, the sample collected reflected adequately the population from which we recruited.

In terms of educational background, 23% (n=13) had left school at 15 with no further qualifications, while 38% had acquired an academic qualification at a diploma, degree or master level (table 2.1).

Table 2.1: Participants educational background

Educational Background	n	%
Left school at 15	13	23
Vocational	10	18
A' Levels	12	21
Diploma	7	13
Degree	8	14
MSc	6	11
Total	56	100

For 38 participants English was their first language (68%). Among the remaining 18 who were not native English speakers, 33% (n= 5) reported their English to be very good while the remaining 77% (n=13) judged their English to be just good.

In terms of sexuality and relationship status, the larger number of participants were heterosexual (n=30, 54%). 30 participants (54%) reported being single. Of those that

were in a relationship, 12% were married and 13% were living with their partner (table 2.2).

Table 2.2: Participants sexual orientation and relationship status

Sexuality	n	%
Heterosexual	30	54
Gay	26	46
Total	56	100
Relationship status		
Single	30	54
Married	7	12
Living with Partner	7	13
Not living With partner	12	21
Total	56	100

55% (n=25) of the participants were living with others such as spouse/partner, family or friends. In terms of residential status 63% were UK residents, 14% were asylum seekers and 12% did not disclose their status (table 2.3).

Table 2.3: Participants living arrangements and residential status

Living arrangements	n	%
Alone	25	45
With others	31	55
Total	56	100
Residential status		
UK national	35	63
Working visa	6	11
Asylum seekers	8	14
Did not respond	7	12
Total	56	100

Finally, information of participants anxiety and depression levels was also collected using the Hospital Anxiety and Depression Scale (HADS). Using Sigmond and Snaith's (1983) criteria, 34% of the total sample scored at the clinical range (i.e scores of 11 and greater) on the measure of anxiety (mean= 8.95, SD=4.38), and 9% on the measure of depression (mean=6.98,SD= 3.18). So, anxiety was more commonly encountered in the participants than depression.

2.3.1.3 Information regarding participants combination therapies

Participants were asked to respond to a series of questions regarding their drug regimens. Their responses to the questions are reported below.

All of the participants had been taking combination drugs for 6 months to 10 years. The mean length of taking combination therapies was 3 years and 2 months (SD = 2.82). The majority of the participants were on triple combinations (n=38, mean=3.36, SD=.98;). 30% reported never having changed their combination drugs, 25% had changed their medication more than two to three times and 20% had changed their combination of drugs 4 to 5 times. Participants were on average taking 10 pills a day (mean=10.82, SD=5.23; Range 28). 66% of the participants reported experiencing side effects such as nausea, headaches, diarrhoea and peripheral neuropathy. 28% reported being greatly bothered by the side effects they experienced. The majority of the participants (70%) reported taking additional medication either to manage the side effects of the combination therapies or for other conditions such as herpes (table 2.4).

Table 2.4: Information regarding participants combination therapies

Times drugs		
Modified	n	%
Never	17	30
Once	10	18
Two to three times	14	25
Four to five times	11	20
Six times	4	7
Total	56	100
Side Effects		
Yes	37	66
No	19	34
Total	56	100
How much do side effects bother you		
Greatly	16	27
Moderately	18	32
Not at all	4	9
No side effects	18	32
Total	56	100
Other medication		
Yes	39	70
No	17	30
Total	56	100

Participants were also asked to report on the strategies that they use to help them remember take their drugs as prescribed (table 2.5).

32% of the participants were using two strategies to remind them to take their medication as prescribed. Self reliance was reported as the most common strategy used by 88% of the participants followed by the use of pillboxes (25%).

Table 2.5: Numbers and kinds of strategies used by participants to help them take their medication as prescribed

No of strategies that help you take your medication	n	%
One	27	48
Two	18	32
Three	10	18
Four	1	2
Kinds of strategies used		
<i>Partner</i>		
Yes	9	16
No	47	84
<i>Self reliance/ memory</i>		
Yes	49	88
No	7	12
<i>Treatment alarm</i>		
Yes	5	9
No	51	91
<i>Pillbox</i>		
Yes	14	25
No	42	75
<i>Part of daily routines</i>		
Yes	14	25
No	42	75

2.3.1.4 Reported levels of adherence

As reported at the Method section of this study, adherence was measured by four variables which for clarity of presentation they will be referred to as follows:

Adh1= Adherence to combination drugs in terms of taking the correct dose
of each drug.

Adh2= Adherence to combination drugs in terms of taking the drugs at the
right time.

Adh3= Adherence to combination drugs in terms of following the dietary instructions.

Adh4= Adherence to combination drugs in terms of taking the right dose of combination drugs, at the right time and in the right way.

In terms of Adh1, 80% (n=45) of the participants reported having taken the right dose of each drug all of the time over the last week prior to the interview while 14% (n=8) reported having taken the correct dose most of the time. In terms of Adh2, 54% (n=30) reported having taken their drugs at the right time all of the time over the last week and 9% (n=5) reported having taken their drugs on time half of the time. 61% (n=34) of the participants had followed the dietary instructions of their combination therapies all of the time and 5% (n=3) had not followed the dietary instructions at all over the last week. Finally, in terms of overall adherence to combination therapies, 52% (n=29) reported having taken their drugs exactly as prescribed all of the time over the last week prior to the interview and 36% (n=20) had taken them as prescribed most of the time (table 2.6).

Table 2.6: Frequencies and percentages for each adherence measure

Adh1	N	%
All of the time	45	80
Most of the time	8	14
Half of the time	1	2
Some of the time	2	4
None of the time	0	0
Adh2		
All of the time	30	54
Most of the time	17	30
Half of the time	5	9
Some of the time	3	5
None of the time	1	2
Adh3		
All of the time	34	61
Most of the time	14	25
Half of the time	4	7
Some of the time	1	2
None of the time	3	5
Adh4		
All of the time	29	52
Most of the time	20	36
Half of the time	3	5
Some of the time	4	7
None of the time	0	0

2.3.2 STATISTICAL ANALYSES AND HYPOTHESES TESTING

2.3.2.1 Reliability analysis of the Health Belief Model (HBM) scale

Internal consistency reliability for each of the six HBM constructs was examined using Cronbach's alpha. The alpha values for severity and cues-to-action constructs were found to be .49 and .51 respectively which indicated low reliabilities for these constructs (Barker and Pistrang, 1994). Thus, overall 5 items –3 from severity and 2 from cues-to-action construct- had to be excluded from the scale because their deletion resulted in a higher value of alpha –as indicated by the “alpha if item

deleted” value. These were items 8, 13, 20, 23 and 41 (see Appendix 3). Results following deletion of items from severity and cues-to-action are presented in Table 2.7.

Table 2.7: Reliability analysis of HBM scale: Cronbach’s alpha

HBM construct	Alpha	No. of items
Severity	.62	2
Susceptibility	.66	7
Benefits	.64	7
Barriers	.78	14
Self efficacy	.81	5
Cues to action	.62	4

Suggested standards for evaluating the reliability of scales indicate that reliabilities of .60 to .70 are marginal, reliabilities of .70 to .80 are acceptable and reliabilities of .80 and above are good (Barker, Pistrang and Elliott, 1994). So with these standards in mind, the reliabilities of the HBM constructs compiled for this study ranged from marginal to acceptable.

2.3.2.2 Data preparation

Data inspection

Prior to analysis all dependent variables were explored for normality with the use of distribution plots and histograms. Consistent with the picture presented by the frequency table described above (table 2.6), it was revealed that all four variables presented highly skewed distributions with most of the participants reporting adhering to the requirements of the drugs all of the time. It was therefore decided to dichotomise the variables and create one group of participants that took the drugs as

prescribed all of the time (adherent =1) and another group of participants who did not take their drugs as prescribed all of the time (non-adherent =2). This is consistent with research that has shown that resistance to combination drugs can be developed by missing even few doses of medication (Rabkin and Chesney 1998). Table 2.8 shows the frequencies and percentages of each adherence measure as dichotomised variables.

Table 2.8: Frequencies and percentages of adherence measures as dichotomised variables

Variable	Group	N	%
Adh1	Adherent	45	80
	Non-adherent	11	20
Adh2	Adherent	30	54
	Non-adherent	26	46
Adh3	Adherent	34	61
	Non-adherent	22	39
Adh4	Adherent	29	52
	Non-adherent	27	48

Furthermore, boxplots were employed to check for abnormalities in the data such as outliers (values more than 1.5 box-lengths away from the box) and extreme values (values more than 3 box-lengths away from the box) that could influence the results and shadow their interpretation. Boxplots for each of the adherence measures and each of the six HBM constructs were thus created. No extreme values were identified. A number of outliers however were evident. These were replaced by the largest or smallest values that were not categorised as outliers, a procedure commonly used to avoid excluding values that can as a result effect the statistical power of the analyses conducted (Tabachnick and Fidell,1996).

Exploratory analyses

Before proceeding to test the hypotheses of the present study a series of analyses were carried out in order to determine possible effects of demographic variables on the outcome variables. These analyses were important in guiding decisions regarding the need to control for the effects of demographic variables in all subsequent analyses.

The effects of the following demographic variables were explored:

age, gender, educational background, relationship status, sexuality, living arrangements, language, and residential status.

Once preliminary examination of the above variables in terms of scatterplots, boxplots and distribution plots were carried out, a t-test for independent samples was employed to explore the relationship between age and adherence measures while χ^2 tests were performed for determining whether adherence measures varied according to the rest of the demographic variables.

The results of the t-tests indicated that there was no significant difference between the adherent and non-adherent group in terms of age across all four measures of adherence (Adh1 $t = .32$, $p = .753$; Adh2 $t = 1.46$, $p = .149$; Adh3 $t = 1.11$, $p = .274$; Adh4 $t = 1.69$, $p = .096$).

Similarly, the χ^2 tests indicated that there were no significant differences in adherence level in any of the four measures of adherence due to gender, educational background, relationship status and living arrangements (Table 2.9).

Table 2.9: Chi-square tests of gender, educational background, relationship status, living arrangements and adherence measures

Demo Variables	adherence	$\chi^2(df)$	p
Gender	Adh1	1.111(1)	.292
	Adh2	.888(1)	.346
	Adh3	.394(1)	.530
	Adh4	.573(1)	.449
Educational Background	Adh1	1.431(2)	.489
	Adh2	.404(2)	.817
	Adh3	4.832(2)	.089
	Adh4	1.233(2)	.540
Relation-Ship Status	Adh1	.098(2)	.952
	Adh2	1.053(2)	.591
	Adh3	.190(2)	.910
	Adh4	3.352(2)	.187
Living Arrange-Ments	Adh1	.004(1)	.952
	Adh2	1.663(1)	.197
	Adh3	.204(1)	.651
	Adh4	1.096(1)	.295

In terms of sexuality, language and residential status a different picture was revealed.

The results indicated that adherence to taking the correct dose of the drugs appeared

to vary according to sexuality [Adh1 $\chi^2(1) = 3.878$, $p=.049$], language [Adh1 $\chi^2(1)$

$=6.225$, $p=.013$] and residential status [Adh1 $\chi^2(1) = 7.912$, $p=.048$]. Examination

of the contingency tables indicated that gay participants, participants whose first

language was English and participants who were UK residents were more likely to

take the correct dose of each drug prescribed. Residential status was also found to be

associated with the overall adherence measure [Adh4 $\chi^2(1) = 8.706$, $p=.033$]. That is

UK residents were more likely to take the correct dose of drugs at the right time and

in the right way than participants who were asylum seekers or refugees.

However sexuality, language and residential status were not significantly associated with the other measures of adherence [Sexuality: Adh2 $\chi^2(1) = .750$, $p = .386$; Adh3 $\chi^2(1) = .204$, $p = .651$; Adh4 $\chi^2(1) = 1.220$, $p = .269$, Language: Adh2 $\chi^2(1) = .136$, $p = .712$; Adh3 $\chi^2(1) = .002$, $p = .967$; Adh4 $\chi^2(1) = 1.767$, $p = .184$, Residential status: Adh2 $\chi^2(1) = 4.906$, $p = .179$; Adh3 $\chi^2(1) = 2.516$, $p = .472$].

On the basis of the above analyses it was decided to control for the effects of sexuality, language and residential status in all further analyses of the Adh1 outcome variable. It was also decided to control for the effect of residential status on Adh4 while no need was indicated to control for the effects of the above demographic variables on the remaining measures of adherence.

2.3.2.3 Exploring the effects of ethnicity, anxiety and depression on measures of adherence

Of particular interest to the present study were the effects of ethnicity, anxiety and depression on participants' adherence to combination therapies since the effects of these variables on adherence have been extensively investigated by previous research studies (Singh et al 1996).

The effects of ethnicity were explored by χ^2 tests. The tests failed to indicate any significant associations between ethnicity and measures of adherence [Adh1 $\chi^2(1) = 1.998$, $p = .157$; Adh2 $\chi^2(1) = .045$, $p = .832$; Adh3 $\chi^2(1) = .421$, $p = .517$; Adh4 $\chi^2(1) = .136$, $p = .712$].

=.259, $p=.611$]. That is, adherence measures did not seem to vary according to whether participants were white or black.

Once normality of the data was explored in terms of distribution plots and scatterplots, the effects of anxiety and depression on adherence measures were explored by t-tests for independent samples. There were no significant differences between the adherent and non-adherent group of participants in terms of anxiety ((Adh1 $t = -.889$, $p = .378$; Adh2 $t = -1.192$, $p = .238$; Adh3 $t = -.948$, $p = .347$; Adh4 $t = -.269$, $p = .789$). Significant differences were found however between the two groups in terms of depression for two of the adherence measures (Adh2 $t = -2.811$, $p = .007$; Adh3 $t = -2.362$, $p = .022$). That is, participants that reported not taking their medication at the right time were found to be more depressed than participants that took their medication on time (adherent group : mean = 5.93, SD = 3.05; nonadherent group: mean = 8.19, SD = 2.94). Similarly, participants that reported not following dietary instructions regarding the taking of the drugs were found to be more depressed than participants who followed such instructions (adherent group : mean = 6.21, SD = 3.19; non-adherent group: mean = 8.18, SD = 2.84). No significant differences were found between the groups for Adh1 and Adh4 variables.

On the basis of the above analyses it was decided to control for the effects of depression in all further analyses of the Adh2 and Adh3 outcome variables.

2.3.2.4 Testing the revised Health Belief Model: predicting adherence to combination drugs

The first research hypothesis is that individuals' adherence to combination drugs can be predicted by the six constructs of the revised HBM. So, in accordance with the model, participants who believe in the severity of HIV/AIDS and feel susceptible to the condition, believe that the benefits of the drug therapies outweigh their costs, have the confidence and utilise strategies to help them remember to take the drugs as prescribed would be more likely to adhere to the combination therapies than those that do not share those beliefs.

To test the above hypothesis multivariate analyses were conducted. Logistic regression was chosen as the most suitable method of analysis because it is a flexible technique which allows prediction of the presence or absence of a characteristic or outcome based on values of a set of predictor variables which can be continuous, dichotomous or discrete (Tabachnick & Fidell, 1996). There no assumptions in force regarding normality or equal variances and a dichotomous dependent variable is required. The present hypothesis was therefore tested for each of the four dichotomous dependent variables and the results were as follows:

Adhering to the correct dose of each drug (Adh1)

A hierarchical logistic regression, with Adh1 as the dependent variable was conducted in which sexuality, language and residential status were entered in the first step and the six HBM constructs were entered in the second step (table 2.10).

Table 2.10: Logistic summary statistics for Adh1 (n=56)

Predictor variable	B	Wald	P Wald	χ^2	df	p for χ^2	Nagelkerke R^2
Step 1				7.91	3	.0480	.209
Sexuality	-.762	.627	.428				
Language	.618	.346	.556				
Residential status	.210	.922	.337				
Step 2				21.96	6	.0012	.658
Severity	-.109	.135	.713				
Susceptibility	-.052	.079	.778				
Benefits	.014	.008	.929				
Barriers	.320	4.18	.041				
Efficacy	.341	1.98	.159				
Cues-to-action	-.612	.212	.645				

Note: χ^2 = change in goodness of fit from step 1 to step 2

The results suggest that after controlling for sexuality, language and residential status, the six constructs of the HBM predicted a further 45% of the variance in adherence level as indicated by comparing the Nagelkerke R^2 tests of step1 and step 2. However, the Wald statistics indicated that none of the HBM constructs had any significant independent effects on Adh1. Wald statistics are not always accurate in their estimates of significance and therefore independent effects were further explored using the model-comparison approach. This approach tests the significant effect of each of the constructs after controlling for the others.

Barriers and cues-to-action were the only constructs that were found to have a significant independent effect on adherence to the correct dose of each drug (barriers: $\chi^2(1)=8.042$, $p=.0046$; cues-to-action: $\chi^2(1)=4.317$, $p=.0377$). That is, after controlling for sexuality, language and residential status, those who reported lower levels of perceived barriers to taking the drugs and greater use of cues-to-action were more likely to take the correct doses of their drugs all of the time.

In order to further explore the lack of independent effects for the rest of the constructs, point-biserial coefficients (r_{pb}) were performed between severity, susceptibility, benefits, self-efficacy and Adh1. Point-biserial correlation is the equivalent of the standard Pearson correlation coefficient and is used in cases where one variable is dichotomous and the other is continuous (Howell, 1997). The results indicated that only benefits and self-efficacy were correlated with Adh1 (benefits: $r_{pb} = -.276$, $p < .01$; self-efficacy: $r_{pb} = -.467$, $p < .01$). So, although those that took the correct dose of their drugs all the time reported more benefits associated with combination therapies and showed greater levels of confidence regarding taking their medication as prescribed, these constructs were not significant as independent predictors of adherence. No associations were found between adherence levels and severity ($r_{pb} = -.036$, $p = .793$) and susceptibility ($r_{pb} = .143$, $p = .294$) which explains their lack of independent effect on adherence.

Taking the drugs at the right time (Adh2)

A second hierarchical logistic regression with Adh2 as the dependent variable was carried out in which depression was entered in the first step and the six HBM constructs were entered in the second step (table 2.11).

Table 2.11: Logistic summary statistics for Adh2 (n=58)

Predictor variable	B	Wald	p for Wald	χ^2	df	p for χ^2	Nagelkerke R^2
<i>Step 1</i>				7.253	1	.007	.162
Depression	.259	6.306	.0120				
<i>Step 2</i>				15.169	6	.019	.441
Severity	-.113	.298	.585				
Susceptibility	-.040	.136	.713				
Benefits	-.265	.4.27	.039				
Barriers	.031	.299	.585				
Efficacy	-.185	1.591	.207				
Cues-to-action	.019	3.017	.082				

Note: χ^2 = change in goodness of fit from step 1 to step 2

The results indicate that after controlling for depression, the six constructs of the HBM predicted a further 28% of the variance in adherence to taking the drugs at the right time as indicated by the Nagelkerke R^2 tests of the two steps.

Examination of the Wald statistics revealed that benefits was the only construct to show significant independent effects on Adh2. That is after controlling for depression, those individuals who reported more benefits from taking the combination therapies were more likely to always take their medication at the right time. The model-comparison approach was used again to further explore independent effects of the remaining five constructs. No significant independent effects were found.

Point-biserial correlations were performed between severity, susceptibility, barriers, self-efficacy, cues-to-action and Adh2. The results indicated that barriers and self-efficacy were highly associated with Adh2 (barriers: $r_{pb} = .350$, $p = .008$; self-efficacy: $r_{pb} = -.449$, $p = .001$). That is those who were always taking their drugs on time reported less barriers to taking their drugs as prescribed and showed great self-

efficacy in terms of taking their drugs consistently. No association were found between Adh2 and severity ($r_{pb} = .058$, $p = .673$), susceptibility ($r_{pb} = .222$, $p = .100$) and cues-to-action ($r_{pb} = -.098$, $p = .471$).

Following the dietary instructions (Adh3)

As with Adh1 and Adh2, a hierarchical logistic regression with Adh3 as the dependent variable was conducted in which the effects of depression were controlled for in step 1 and the six HBM constructs were entered in the second step (table 2.12)

Table 2.12: Logistic summary statistics for Adh3 (n=58)

Predictor variable	B	Wald	p for Wald	χ^2	df	p for χ^2	Nagelkerke R^2
<i>Step 1</i>				5.031	1	.025	.116
Depression	.218	4.499	.034				
<i>Step 2</i>				4.138	6	.658	.205
Severity	.003	.002	.988				
Susceptibility	.103	1.105	.293				
Benefits	.019	.038	.845				
Barriers	.047	1.018	.313				
Efficacy	.038	.085	.770				
Cues to action	.129	1.258	.262				

Note: χ^2 = change in goodness of fit from step 1 to step 2

The results indicated that after controlling for depression the six constructs of the HBM accounted for a further 9% which however was not found to be significant.

That is, the HBM as a set of six variables failed to predict adherence levels to dietary instructions regarding combination drugs.

Furthermore Wald statistics and model-comparisons failed to indicate any significant independent effects of the HBM constructs on Adh3. Point-biserial correlations revealed that only barriers were significantly associated with Adh3 ($r_{pb} = .276$,

p=.040). That is those that have always followed the dietary instructions of their medication were more likely to report less barriers to taking their medication as prescribed.

Overall adherence to taking the drugs as prescribed (Adh4)

Finally, adherence to taking the correct dose of the drugs, at the right time and in the right way was also explored using a hierarchical logistic regression with Adh4 being the dependent variable. Residential status was entered in step 1 and the HBM constructs in the second step (table 2.13).

Table 2.13: Logistic summary statistics for Adh4 (n=58)

Predictor variable	B	Wald	p for Wald	χ^2	df	p for χ^2	Nagelkerke R ²
Step 1				6.448	1	.011	.145
Residential status	.318	5.695	.017				
Step 2				12.708	6	.048	.386
Severity	.045	.188	.810				
Susceptibility	-.057	.285	.593				
Benefits	-.115	.999	.317				
Barriers	.103	3.343	.066				
Efficacy	-.180	1.538	.215				
Cues to action	.015	.015	.902				

Note: χ^2 = change in goodness of fit from step 1 to step 2

The results suggest that after controlling for depression the HBM constructs predicted a further 24% of the variance in the Adh4. As with the other adherence measures, the Wald statistics and model-comparisons were used to ascertain the independent effects of the HBM constructs. The results indicated that only barriers made a significant independent contribution to the Adh4 ($\chi^2(1)=3.830$, p=.0503).

That is, those that perceived less barriers with taking their medication were more likely to take the correct dose of the drugs at the right time and in the right way.

Point-biserial correlations between the HBM constructs and the Adh4 revealed that severity, susceptibility, and cues-to-action were not significantly associated with adherence to taking the drugs as prescribed (severity: $r_{pb} = -.027$, $p = .842$; susceptibility: $r_{pb} = .101$, $p = .461$; cues-to-action: $r_{pb} = .020$, $p = .882$). However, benefits, and self-efficacy were found to be highly associated with Adh4 (benefits: $r_{pb} = -.310$, $p = .002$; barriers: $r_{pb} = .402$, $p = .002$; self-efficacy: $r_{pb} = .020$, $p = .882$). That is, those that perceived more benefits in taking combination therapies and felt more confident in taking their drugs as prescribed were more likely to always adhere to their medication.

Overall, the HBM as a set of predictors distinguished between the adherent and non-adherent participants for the Adh1, Adh2 and Adh4 measures but not for the Adh3. The barriers construct had a significant independent effect on Adh1, Adh2, the benefits construct made a significant independent contribution on Adh2 and finally, cues-to-action was shown to have an independent effect on Adh1. Self-efficacy was found to be strongly associated with Adh1, Adh2 and Adh4. Severity and susceptibility however were not associated with either of the four adherence measures.

2.3.2.5 Comparing the original and revised versions of HBM

The second hypothesis of this study relates to the extent that the addition of self efficacy and cues to action to the four constructs of the original HBM –severity, susceptibility, benefits and barriers- would improve the overall predictive power of the HBM.

This hypothesis was tested only on the three adherence measures that were found in the previous section to be significantly predicted by the six constructs of the HBM, that is Adh1, Adh2 and Adh4. Thus, three logistic regressions were performed. The variables that needed to be controlled for were entered in the first step, severity, susceptibility, benefits and barriers were entered in the second step and self-efficacy and cues-to-action were entered in the third step. Table 2.14 shows the results of the second and third step.

Table 2.14: Logistic regression summaries comparing original and revised HBM

	χ^2	df	p for χ^2	Nagelkerke R^2
Adh1				
Step2	16.803	4	.0021	.567
Step 3	5.165	2	.0756	.658
Adh2				
Step 2	13.190	4	.0104	.408
Step 3	1.979	2	.3717	.441
Adh4				
Step 2	10.994	4	.0266	.357
Step 3	1.714	2	.4245	.386

Note: χ^2 = change in goodness of fit from step 1 to step 2 and step 2 to step 3

The results indicated that the addition of efficacy and cues to action to the four constructs of the original version of the HBM made a small contribution to the

prediction of the three adherence measures (Adh1= 9%, Adh2= 3%, Adh4= 3%). However, none of these contributions were found to be significant and therefore it can be concluded that compared to the original HBM, the revised HBM did not significantly account for greater variability in adherence with combination drugs.

2.3.2.6 Testing the revised HBM as an interactive model

The third hypothesis explores the moderating effect of severity on the relationship between the susceptibility, benefits, barriers, self-efficacy and cues-to-action and measures of adherence. Similarly to the second hypothesis explored above, this hypothesis was tested only for the three adherence measures that were previously found to be predicted by the six constructs of the HBM, that is Adh1, Adh2 and Adh4.

In order to test for moderation, hierarchical logistic regressions were once more conducted. These procedures allow for the testing of interactions between the independent and the moderating variables by partialing out their main effects (Cohen and Cohen, 1983). The logistic regressions involved three steps. In the first step the variables that needed to be controlled for in each adherence measure were entered. The second step contained the six HBM constructs while the third step contained the interactions between severity and each of the remaining HBM variables. Table 2.15 shows the results of the third steps.

Table 2.15: Logistic regression summaries for severity as a moderator variable

	x²	df	P for x²
Adh1			
Sever * susceptibility	.369	1	.5435
Sever * benefits	.368	1	.5443
Sever * barriers	1.592	1	.2071
Sever * efficacy	.101	1	.7510
Sever * cues	1.182	1	.2769
Adh2			
Sever * susceptibility	1.160	1	.2815
Sever * benefits	3.303	1	.0691
Sever * barriers	2.128	1	.1447
Sever * efficacy	.037	1	.8470
Sever * cues	.621	1	.4306
Adh4			
Sever * susceptibility	.018	1	.8926
Sever * benefits	.002	1	.9636
Sever * barriers	.396	1	.5292
Sever * efficacy	1.536	1	.2152
Sever * cues	1.912	1	.1667

Note: x² = change in goodness of fit from step 2 to step 3

The results indicated that severity did not moderate the effects of the HBM constructs on the three adherence measures. That is severity was not found to be a significant moderator in the relationship between HBM constructs and levels of adherence.

CHAPTER THREE: A QUALITATIVE STUDY OF THE FACTORS CONTRIBUTING TO NON- ADHERENCE IN BLACK AFRICAN USERS OF COMBINATION THERAPIES

3.1 OBJECTIVE

To date there is limited understanding of the specific factors that could account for differences in adherence levels among individuals from different ethnic backgrounds. This part of the present research study aims to explore the factors that may account for the reported low adherence rates among black users of combination therapies as presented and discussed at the introduction section.

3.2 METHODS

3.2.1 Study design

A qualitative method of inquiry was used for this part of the study. It has been argued that qualitative methods are especially useful for exploratory research where little is known about the phenomenon of interest (Stewart and Shamdasani, 1990).

Focus groups were planned to be used as the primary source of data collection. Krueger (1994) defined focus groups as “carefully planned discussions designed to obtain perceptions on a defined area of interest in a permissive and non-threatening environment” (p6). These groups consist of interactive group discussions with an

investigator acting as a facilitator to optimise exchanges between members of the group and prompt group members to expand on ideas, clarify points and develop insights which may not originally have seemed of major importance to individual members of the group (Kitzinger,1994). What differentiates focus groups from other forms of qualitative data collection is primarily the presence of group interaction in response to researchers' questions. In addition, the participants selected tend to have certain characteristics in common that relate to the topic of the focus group discussion. Thus, gathering information in this way taps into a collective experience and the analysis of the participants' responses can provide important clues and insight into the area under investigation (Krueger, 1994).

3.2.2 Participants

Multiple groups, typically composed of 6-10 people who are similar to each other, are needed to detect patterns and trends across groups (Krueger, 1994). The present study aimed to conduct three focus groups with 6-8 black users of combination drugs in each.

Participants recruited to complete the study's questionnaires were also asked whether they would like to take part in a group discussion regarding their experiences of taking combination drugs. Among the 25 black participants that agreed to complete the questionnaires, 7 of them agreed to take part in a focus group. Thus, it was only possible to run one focus group.

A date and time for the focus group was set and the 7 participants- 5 women and 2 men- were sent an invitation to attend. The focus group took place at a drop-in center for African communities as most of the participants were regularly users of the center and African food and crèche facilities were on offer.

The participants ranged in age from 25 to 48 years (mean age: 34) and they were all black Africans taking combination drugs for 6 months or more.

3.2.3 Materials

The specific content of the questions was generated from the review of the literature and previous research regarding adherence levels among ethnic minorities and from consultation with clinicians such as psychologists, doctors and nurses working with black users of combination therapies. The content of the focus group questions was organised around four broad research themes:

A. Black users' understanding of adherence to combination drugs.

The question employed to address this theme aimed to explore participants' understanding of adherence to the drugs and allow them to reflect on the complexities involved in taking combination drugs as prescribed.

B. Black participants' experiences of taking combination drugs.

This theme was explored by employing a series of questions to assess participants decision making process regarding starting on combination therapies, alongside their experiences of the benefits and difficulties of taking the drugs.

C. Reasons for explaining lower levels of adherence to combination drugs in black users.

This research theme focused upon assessing participants' views regarding black people's beliefs about HIV and AIDS, combination therapies and traditional therapies. In addition, the questions asked aimed to explore participants' views regarding the possible reasons that could account for the reported lower levels of adherence found in black users of the treatments.

D. Best ways that black users of combination drugs can be supported to take the drugs as prescribed.

Questions on this theme asked participants to reflect on what they have found useful in helping them take their medication as prescribed. Moreover, participants were also asked for their views and feelings regarding systems of support for black users of combination therapies.

Once an initial set of questions and a moderator's guide for facilitating the focus group was compiled, the focus group format was field-tested by having experts

familiar with the study and the participants (a clinical psychologist and the director of UMOJA drop-in centre) review the logical and sequential flow of the questions and the ability of the probes to elicit the information desired, a process recommended by Kreuger (1994). In this way we were able to ensure that questions were appropriately phrased in terms of clarity, precision and brevity (see Appendix 7).

3.2.4 Procedures

In order to ensure that participants were comfortable taking part in a focus group and felt able to talk freely about their experiences of taking combination therapies, the researcher visited the center on two occasions prior to running the group, to introduce herself to them and familiarise them with the aims and procedures of the study.

The actual focus group lasted approximately 2 hours and was conducted by one researcher, who acted as the moderator. Her role was to ask the open-ended questions as planned, probe for additional comments and monitored the group discussion. At the same time she kept track of the time and kept notes on participants' responses.

It is recommended that the focus group interviews are audiotaped and fully transcribed for later data analysis (Krueger, 1994). However, it was not possible to follow this suggestion since the participants did not permit the audiotaping of the discussion in fear that they could be identified by their voices. Despite attempts to

reassure everyone that taping was only for ensuring the accurate transcription of their responses and the tape was going to be erased soon after the transcriptions were completed, participants did not agree to taping.

As a result participants responses were recorded on paper as close to verbatim as possible. Additional summary notes were also kept immediately after the focus group had ended regarding the main themes that emerged during the focus group and the general atmosphere and emotional responses of the participants in an attempt to enrich the quality of the notes taken during the running of the focus group.

3.2.5 Data analysis

A qualitative summary of participants comments was the primary method of analysis for this study (Morgan, 1988). The summary involved reviewing all the field notes and summary notes to identify themes that emerged from participants' responses in relation to each question as well as themes that run across the focus group interview.

However, since only one focus group was conducted, it was not possible to use established qualitative data analysis computer programs such as Ethnograph. Thus, the present analysis aimed to primarily provide a flavour of what the black participants had to say about their experiences of taking combination therapies.

3.3 RESULTS

It was decided to summarize and present participants comments as provided in response to each of the interview questions. Moreover, the general themes that run throughout the interview will also be identified and discussed. Participants responses have been generously quoted to both reinforce suggested themes and to give voice to the black users of combination therapies participating in the study.

3.3.1 Participants responses to the interview questions

A. Black participants' understanding of adherence to combination drugs.

What do you understand by “compliance or adherence to combination drugs”

All participants agreed that adherence was all about taking the medication that one is prescribed by the doctors. As the participant who first responded to the question explained:

“ it is about sticking to the medication whatever the matter”. Another participant added “ you should not change it (the medication) unless advised to”.

Non-adherence was defined in terms of *“not taking the drugs”, “ skipping doses”, “not taking the drugs regularly”, “taking them at random” or “not sticking to the dose”.*

The majority of the participants pointed out difficulties regarding adhering to the time requirements of the drugs: “ *I often not stick to my time and forget to take the evening one*”. Social circumstances were reported as being the main reason for not adhering to time requirements such as being at a restaurant or socialising and so “*you can’t take your drugs*”. Others reported that the time requirements were very inconvenient to keep up with: “ I have to take the drugs at 12 noon and 12 at night. I can’t cope with taking them so late”.

Dietary requirements were not thought as important as taking all the drugs at the right time:

“ *I have to take some drugs on an empty stomach but if I am hungry I’ ll eat and take them later*”.

Many participants noted that they did not have any specific dietary instructions to follow. All participants seemed to agree that drug taking requirements needed to be “suitable to the individual needs” to ensure successful adherence.

B. Black participants experiences of taking combination drugs

What has made you decide to take combination drugs?

The majority of the participants felt that they did not have a choice over taking the drugs. For them the severity of HIV implied that one can not fight HIV without the drugs. As one participant put it *“the CD4 and T-cells and virus loads in essence decide for you, and the doctors pressure you into taking them.”*

Similar explanations were provided by other participants:

“ the doctor asks you whether you want to take drugs but really you have no choice”

“ It is like as if you need a blood transfusion, you are dead if you don’t have it”.

For most participants therefore the “fear of death” was identified as the main deciding factor for starting on combination therapies.

What will you say the benefits of taking combination therapies are?

Participants reflected on the ability of the drugs to suppress the virus by preventing multiplication so that the virus reduces and becomes undetectable, although it was unanimously acknowledged that the drugs *“can not get rid of it (HIV)”*.

Participants went on to identify a range of health related benefits such as preventing flues and colds, infections and tiredness. Few of the participants also pointed out that

taking the drugs meant “*buying time for life*”, “*giving time to enjoy life and self*”, allow to “*live as if you have no symptoms*” and thus extending life expectancy and improving quality of life.

Participants also discussed the importance of staying positive and as one participant added: “one day we could fight it”. So, for the participants combination drugs offer the chance of longer and better life alongside the hope of a cure.

What are the difficulties of taking the drugs?

Participants were very forthcoming with regards to the difficulties that they experienced from taking combination drugs both at a physical and psychological level. A range of side effects were identified such as nausea, vomiting, headaches, chest pains, skin and nails discolouring, itchiness, rashes, brittle nails, breathless, neuropathy, swelling of ankles, enlargement of breasts, lypodystrophy and kidney complications. Additional side-effects were bad dreams, panic attacks and terrors.

A few participants also pointed out that the side effects of the drugs had disrupted their social and everyday life. So, as one participant said “they make me breathless and then I can not go up stairs”. For another participant the effects of the drugs on her physical appearance had made her stop taking the drugs. For some participants work was also affected by the need to take the drugs “it is a catch 22 situation because you can’t stop working and so you do not take the drugs”.

Participants also commented on the complexity of the drug regimens and pointed out that “drug routines are difficult to follow”. Few participants went on to point out that they felt the drugs were particularly made to fit “white people’s routines” and that “Africans have never been consulted” in relation to these drug regimens. Their feeling was that African people are “not as regimental as white people” and as a result they have a more lay back attitude towards medication. As one participant explained “if you ask a black person to take drugs at 8.00 am, it maybe 9.00am when he starts thinking he has to take his drugs and 10.00 am by the time he manages to take them”.

Participants thus identified a range of side-effects and inconveniences regarding taking the drugs alongside some scepticism regarding the extent that these drugs are appropriately targeting black individuals with HIV.

C. Reasons for explaining lower levels of adherence to combination drugs in black users

What are the reasons that would make black individuals less likely to take combination drugs as prescribed?

Three main themes emerged from the participants responses to this question and serve to highlight the complex involvement of a combination of factors in nonadherence to combination treatments. These themes related to social and economic circumstances, issues of disclosure and side-effects.

The majority of participants referred to the specific social and economic circumstances that make taking medication as prescribed difficult to adhere to. Most participants explained that their residential status as refugees or asylum seekers meant that they had to spend many hours and in many cases days queuing at the home office, or waiting at the DSS office. As a result whole doses are easily missed or forgotten. Very often the anxiety and stress of an uncertain residential status and the housing and economic consequences of it, forces individuals to neglect their health responsibilities. Health stops being a priority. As one participant put it *"I worry more about whether my children have food or whether I have to go to the home office rather than go to the doctor's and take my medication"*.

Issues of disclosure were reported as very important in determining whether one would take their medication as prescribed. Participants contrasted their cultural circumstances with those of the gay community in terms of an open acceptance of their HIV status and the taking of medication. One participant elaborated on the subject by saying:

"the first people to have HIV were gay people and they don't mind taking the drugs, but we have our own culture and background and we haven't accept it yet we are not open about it... .. we are still hiding from family and community we can't be open about taking them (combination drugs), there is lots of fear and stigma".

Another participant added:

“Most do not even tell their partners..... or if both are treated they will be attending different hospitals”.

Most participants supported the fact that disclosure issues makes taking the drugs when in the company of others very difficult and in most cases impossible. Some participants explained that if they have to take medication in front of others they tend to conceal the purpose of the medication by providing alternative explanations for taking it i.e. migraine, stomach problems or kidney infections. This was particular true for those who were sharing accommodation space with others:

“ if you are a refugee or asylum seeker living in hostels and Bed and Breakfast places with many others, it is difficult to take the drugs because they will want some, so you lie”.

Moreover, some participants also pointed out that economics affects the ways that people relate to each other. The lack of financial resources often dictates the sharing of everyday living supplies including medication:

“If you go to gatherings with other black Africans is difficult to explain why you are taking the drugs, you may say it is for a headache...., they often may say I have one, can I take some of that medication , so it is common to exchange medications for what ever it is for... for example if I take a paracetamol, they will want one... if I explain it is for my kidneys or itchiness they will still want some”

“if I take my medication in front of my friend, she would ask me what is it for and would want some... and if I do not give her some she could write the name down and go and find out what it is”

“you see, we share many things with others it is our culture...”.

As a result the majority of participants reported preferring not to take their medication at all when with others. There was however a split in how participants dealt with the above difficulties. Some participants reported making an effort to excuse themselves when in the company of others and find a private space to take their medication:

“ I always have my medication in my bag... .. I can go to the toilet and take them and no one will know”.

Others did not feel as able to do the same and would as a result miss or delay taking their medication:

“..in African communities women have long discussions with each other... .. and when I am talking with friends I will not interrupt to take my medication or leave to go home to take the drugs... It is the social norms...”

Finally, in terms of the effects of side effects on adherence participants explained that becoming ill or feeling unwell would lead them to stop or modify their

medication: *"I stopped the drug because I had stretch marks in all my body and I couldn't take it anymore"*. Most of the participants pointed out however that they had stopped or changed medication due to side effects only after consultation with their doctor. Side-effects were identified as more important than beliefs about severity of HIV and AIDS.

Do you think that black people have different views or ideas about HIV and AIDS than others, that make them not take the drugs as prescribed?

All participants commented on the fact that in Africa HIV is only known as AIDS and it is associated in everybody's mind with death. Moreover, participants pointed out the stigma that HIV and AIDS carries among Africans and the associations with prostitution, and promiscuity. Some participants also commented on the implications of an HIV diagnosis on the family and how in many instances individuals would hide their HIV status from their partner in fear of rejection and stigmatisation:

"If I tell my mother I am HIV she will think I am dying, she won't understand"

"If people know you have HIV, they start wondering about how you got it, and think you have been sleeping around"

"I've heard of couples that are both HIV but they have not told each other, and they may even be treated at the same hospital"

Thus, the stigma associated with HIV and AIDS was argued by participants to be the major factor influencing medication taking, by making individuals avoid take their medication when others are around.

Do you think black people have different ideas and beliefs about combination drugs than others that make them not take them as prescribed?

The experience of side effects attributed to combination drugs was given as a reason for why many users were put off from taking the drugs. As one participant explained “when you take medication you should feel better, not worse”.

Participants explained that especially in Africa people are sceptical regarding the effectiveness of the drugs and westernised treatments in general. They went on to explain that information regarding the benefits of combination drugs tend to be communicated by word of mouth and it usually biased by personal experiences and the lack of adequate information regarding the HIV and the drugs. Indeed most participants agreed that this was the most important route of knowledge about the illness and related treatments among Africans, especially for those with limited understanding of the English language: “... *word of mouth goes very fast...*”. If people are seen to receive hospital based treatments with westernised medication and then die, misconceptions regarding what the drugs can do are then created that foster mistrust in these medications:

“ ...*people go to hospital and then die and ... people come and say to you, I spoke to him yesterday and he was well and then he went to the hospital and gave him the*

wrong medication and now he is dead... ..but it is not the medication... .. people never expect that it may be that these people had the virus and they were diagnosed late ... so create mistrust in medication”.

Do you think black people are more likely to use traditional remedies than western ones?

Participants explained that in South Africa where financial resources are limited and westernised medication for HIV is expensive, herbal remedies are the popular alternative:

“ people use herbal medication and if they have money they may use westernised medication as well... ”

Cows feet was reported as one such remedy that all participants were aware off. Ginger and garlic were also reported as widely used although participants underlined mostly the psychological effects of using such remedies rather than as form of managing the illness:

“people think that these (ginger and garlic) are cleansing and give you strength and so are useful from a psychological point of view... ..”

“ you use cow foot and boil them and ... it creates a gelatin ... it is like thick soup that you can eat... ”

Some of the participants reported using some of these remedies but never to replace the taking of combination drugs.

Chinese herbal treatments and acupuncture were also reported as very popular among Africans. All participants were aware of the benefits of Chinese therapies and many reported using them for the relief of eczema and side-effects:

“Chinese remedies are very good... they are very successful with skin eczema and feeling sick from taking the medication (combination drugs) but they are very expensive”.

None of the participants reported having replaced combination drugs for Chinese treatments. They were primarily seen as useful complementary therapies rather than alternatives to combination drugs.

From all the reasons for why black users of combination treatments are less likely to take the drugs that we discussed, which one would you say is the most important to keep in mind?

Participants referred once more to the cultural, social and economic factors that can affect consistent adherence to taking medication as prescribed. The fear of stigmatisation and the close interactional relationships among Africans were presented as the most important obstacles in taking the drugs and keeping up with the requirements of the drug regimens:

“ it has to do with our cultural background... ..we are not as open about talking about HIV and taking the drug... .. ”.

D. Best ways that black users of combination drugs can be supported to take the drugs as prescribed

What things help you take your drugs as prescribed?

Participants made the point that using strategies to help one remember to take the medication depended on how open one is regarding taking medication around others and once more they contrasted themselves to gay individuals and the strategies that they use:

“ I have been on a conference where beepers will go off and I will turn my head and see people taking their drugs... but these are gay people that do not mind taking them in front of others... ”.

Most participants reported relying on their memory rather than using alarms and treatment diaries. Few participants were using pill boxes and for most participants the most helpful strategy was having incorporated the taking of their medication in their daily routines:

“if I am at home I check the clock regularly or know from the TV programs when to take my medication”.

What would be helpful in supporting black clients to take combination drugs as advised?

Four main areas of support were discussed as relevant in helping black clients with taking combination therapies. These involved the design of the drugs, the availability of appropriate information regarding the drugs, the presence of peer support groups and the improvement of doctor-client relationship.

Most participants agreed for the need of drugs that had fewer side-effects, were easier to take and that were also trial tested on Africans to ensure suitability for their immune system. One participant even suggested a depo injection – an injection of slow releasing medication- as a solution to the inconvenient drug taking routines characteristic of the combination drugs regimens.

Information regarding the available treatments was also seen by the participants as important in combating the biased views that many black individual with HIV have formed by word of mouth information. Few participants pointed that many black users of combination therapies expect the drugs to be magic and feel that the virus will go away in few days. As one participant explained:

“people need information about why they take them (the combination drugs), how long they need to take them for and all that... ..because you can change (combination of drugs) many times.....”.

Peer support groups were also reported as an important source of support. They were perceived as useful forums for meeting other HIV positive Africans on combination therapies, for exchanging information regarding the drugs, for empowering individuals to take their medication and address adherence difficulties with their doctors. Moreover, for most participants attending peer groups had helped them to deal with the fear of stigmatisation and isolation at a psychological level. For the majority of participants sharing experiences of illness and medication had been a strengthening experience:

“Peer support and groups such as this one (the UMOJA drop-in center for African communities) are very helpful. “

“ I was very secretive but coming here has encouraged me to be open”

“I have benefited psychologically from coming here ... I preferred to shut myself in my room.... coming here is helpful, I do not suffer alone now”

“I can’t discuss it with my best friend, she can’t understand... so coming here I can talk about medication and I can go back to my doctor and discuss any issues or difficulties I have with medication”

“ more black/ethnic friendly environments are needed especially in HIV clinics” .

Finally, improvements in the doctor-patient relationship were suggested by most participants in order to ensure collaborative relationships. These were seen as important in empowering clients to take responsibility about their treatments. Moreover, it was felt that doctors needed to be more aware of community agencies for African people with HIV and facilitate supportive links with the community:

“doctors need to listen and spend more time talking to people”

“clients need to know their rights.... there must be a negotiating relationship with the doctor... .. so I am able to say if the drugs are not ok for meable to talk to them and not be patronised”

“doctors tell them to take the drugs but they do not ...they say they do as they see doctors as experts and they are afraid to say no but then at home they do not take the drugs”

“If doctors do not know about services how can they recommend or encourage people to join groups... .. and get help... .”

3.3.2 Summary Findings

All 7 participants contributed greatly in the questions asked. They all seemed very interested in the discussions generated and were all willing to express and discuss

their experiences of HIV and combination therapies. The fact that most of them were familiar with each other was probably an important factor in establishing a friendly, supportive and non-threatening environment which fostered the open, honest and at times humorous communication of views, beliefs and experiences. Participants commented at the end of the interview on how much they had enjoyed the group discussion.

In reviewing participants' responses and summarising the findings the following general themes emerged as important contributors in the understanding of black users adherence to combination therapies. These themes did not only emerge as responses to the specific questions of the interview but seemed to run across the discussions generated in response to most questions asked.

The theme of adherence to combination drugs as an important factor for managing symptoms of ill health and for prolonging life was raised by the majority of the participants. Thus, the physical and psychological effects of taking the drugs were greatly acknowledged despite their side-effects on health and everyday functioning. Moreover although traditional remedies were referred to they were primarily considered as complementary treatments rather than alternatives to combination drugs. In addition, the "fear of death" was another theme that emerged as an important motivating factor in participants' decision to start on combination therapies and continue their use as prescribed. Both these themes serve to underline the participants' views about the severity of the HIV condition and to some extent their belief in the potential effects of combination drugs on their health.

In terms of non-adherence to combination therapies among black African users, the theme related to the fear of stigmatisation and rejection by others in the community prevailed among participants' responses in relation to a number of interview questions. Participants saw fear of stigmatisation as the main obstacle in disclosing their HIV status to others around them and as a result it effected their ability to openly take their medication in front of them. These difficulties with taking the drugs are further exacerbated by the socio-economic circumstances of many of the African users of combination therapies that implied the absence of private time and space that could facilitate the taking of the drugs as prescribed. Participants however, were divided in terms of how they overcome these difficulties. Some felt able to withdraw from the company of others and find some private space for taking their medication while others opted for delaying or missing their drug dose altogether.

Finally, a small number of participants identified the side effects of the drugs as a factor in non-adherence to the combination treatments. Some scepticism regarding the suitability of the drugs with African users in terms of fitting with their non-regimental attitudes to life and medication taking as well as in terms of side effects on health was expressed.

In terms of strategies and support systems that facilitate adherence to combination therapies by black users, most participants reported relying on their memory for taking the drugs as prescribed as the use of alarms, beepers and pillboxes makes the process of drug taking more noticeable by others around them. In relation to support available to black users the theme that emerged was that peer support groups were very helpful in dealing with many of the difficulties and anxieties faced by African

uses of the drugs as expressed by the themes presented above. However, participants identified a number of areas that needed to be further developed and these included the availability of information regarding HIV and treatments and most importantly the improvement of the doctor –patient relationship.

Finally, participants throughout the interview frequently contrasted themselves to the gay users of the same treatments in terms of acceptance of the HIV condition and the taking of combination drugs. They clearly saw their experiences of HIV and combination therapies as distinct from those of gay or other white individuals and as heavily influenced by their specific cultural and social circumstances.

CHAPTER FOUR: DISCUSSION

4.1 OVERVIEW

The present research study aimed to investigate adherence to combination therapies for individuals with HIV and AIDS. Clinical trials outcomes and research findings into anti-HIV drugs have served to highlight that combination therapies demand a high level of patient adherence “for life” to ensure that the medication is effective and HIV resistance to the drugs is minimised or avoided. At the same time the research findings today also acknowledge that the required levels of adherence to these treatments are not always easy to achieve and maintain.

The first aim of the present study was to investigate adherence to the combination therapies using the Health Belief Model as its theory-based framework. With this model in mind, it was hypothesised that adherence to combination therapies can be predicted by the individual’s beliefs of the severity of HIV and AIDS, their perception of how susceptible they are to the condition and their perception of the costs and benefits of taking their medication as prescribed. In addition, and in accordance to the revised version of the model, it was also hypothesised that adherence can be predicted by the individual’s confidence in their ability to adhere to all the requirements of taking the drugs alongside their ability to use strategies to ensure that they remember to take their medication. A quantitative study was therefore designed to address this first aim and test these hypotheses.

Moreover, in light of findings indicating poor adherence levels with combination therapies among ethnic minorities and especially black individuals, the present study set out as its second aim to explore the factors that may contribute to these differences in adherence by a focus group based qualitative study.

Having presented the results of both studies in the previous two chapters, the present chapter aims to integrate these results and discuss them in the light of the findings of previous studies. Moreover, the implications of the present study's findings are going to be considered followed by the limitations of this study and recommendations for future research initiatives in the field of adherence to combination therapies.

4.2 THE HEALTH BELIEF MODEL AND ADHERENCE TO COMBINATION THERAPIES: DISCUSSING THE RESULTS OF THE QUANTITATIVE STUDY.

4.2.1 An overview of the main findings of the quantitative study

Adherence to combination therapies was assessed using four measures of adherence. Each of these measures was assessing a different aspect of adherence to the anti-HIV drugs namely, adherence to taking the correct dose of each drug, keeping to the right time, taking the drugs with or without food and an overall measure of taking the drugs as prescribed. The findings indicated that in terms of overall adherence, 52% of the participants reported always taking their drugs as prescribed that is, taking the

right dose, at the right time and in the right way. However, when participants were asked to report their levels of adherence to taking the correct dose of each of their drugs alone, levels of reported adherence increased to 80%. Adherence levels however for taking the drugs at the right time was 54% and for following dietary instructions 64%.

Since the present study recruited from an ethnically and culturally diverse population, almost half of the sample (45%) were black participants. This permitted the exploration of possible differences between black and white individuals in terms of adherence to combination drugs. The results of t-test analyses indicated that ethnicity was not significantly influencing adherence measures. That is black and white participants did not differ in their adherence levels in either of the four adherence measures.

A wide range of demographic data were collected and their effects on adherence measures was explored. In addition, participants anxiety and depression levels were also assessed. Chi-square analyses indicated that language and sexuality were significantly associated with adherence to taking the correct dose of the drugs. That is gay participants and those whose first language was English were more likely to adhere to the right dosage of their drugs. Moreover, residential status was significantly associated with adherence to taking the correct dose of the drugs and overall adherence levels. That is those who were UK nationals were more likely to take their drugs in the right dosage and to report higher levels of overall adherence compared to those who were asylum seekers or refugees. Finally depression was significantly associated with adherence to time and dietary requirements. That is,

individuals that scored higher on the depression scale were less likely to take their drugs at the right time or follow the instruction regarding taking their drugs with food or on an empty stomach.

In terms of testing the predictive power of the HBM, logistic regression analyses indicated that with the exception of dietary instructions, the HBM as a set of six variables significantly predicted adherence to taking the correct dose of each drug and adherence to taking the drugs at the right time. Moreover, the HBM was found to predict 45% of the variance in overall adherence levels.

When the main effects of the six constructs were further explored it was found that the barriers construct significantly predicted adherence to taking the right dose of each drug and adherence to taking the drugs as the right time. The benefits construct was found to predict adherence to taking the drugs at the right time. The cues-to-action construct was also found to predict taking the correct dose of each drug. The construct of self-efficacy although not found to independently predict adherence to either of the three measures, it was nevertheless strongly associated with all of them. Finally, severity and susceptibility were not found to be independently predictive of either of the adherence measures. In fact point-biserial correlations showed that these two constructs were not associated with the adherence measures employed in the present study.

In terms of comparing the original and revised HBMs, the results of the logistic regression indicated that the addition of self-efficacy and cues to action to the original model did not significantly add to the predictive power of the HBM for

either of the adherence measures. That is neither of these constructs made a significant contribution to the variance accounted by the constructs of the original HBM.

Finally, the present study took up the challenge to further explore the role of severity as a moderator factor between HBM constructs and adherence measures. However, the results of hierarchical logistic regressions indicated that severity did not act as a moderator factor. That is severity did not seem to influence the strength of the influence of any of the HBM constructs on the adherence measures.

4.2.2 Interpretation of the main findings

Adherence levels reported in the present study

The present findings indicated that participants were primarily taking all their drugs but were not necessarily taking them at the right time or with the right food. In fact, when they were specifically asked if they were adhering to the time and dietary requirements of their medication the adherence levels reported were much lower than the adherence levels for taking all the drugs at the right dosage.

The present findings are in line with previous research findings indicating levels of adherence with medication for other conditions and with anti-HIV drugs in the range of 40-80 % (Rabkin and Chesney, 1998). To date however, research findings regarding adherence levels to self-reported measures of the time and dietary requirements of the combination drugs are not available since most definitions of adherence in these studies did not take these requirements into account (Samet et al,

1992; Aversa and Kimberlin, 1996). However, in light of reports indicating that high levels of adherence to all the requirements of the combination drugs are required for the drugs to work, the present findings indicated that a large percentage of the participants were not fully benefiting from receiving these treatments. Furthermore they were also in danger of developing resistance to the drugs that they were taking.

What is particularly interesting in terms of the present findings is the fact that they serve to underline the complexity involved in adhering to combination drugs and the importance of assessing each aspect of adherence to combination therapies separately. It is only by the exploration of each of these aspects that a representative picture of the difficulties that individuals face regarding taking their medication can be achieved.

Testing the HBM

The findings of the present study indicated that the constructs of the HBM significantly predicted overall measures of adherence as well as adherence to taking the correct dose of each drug and taking the drugs at the right time. However, in terms of individual predictors of adherence to these three measures, not all six constructs were found to be significant. So, the current results showed that those individuals who perceived less difficulties (barriers) with taking the drugs were more likely to take their combination drugs at the right dosage and moreover they were more likely to show higher levels of overall adherence to the medication. In addition, the present results also showed that those individuals who perceived greater benefits from taking the combination drugs as prescribed were more likely to take their drugs at the right time.

It seems therefore that for individuals to decide to take the right dosage of drugs it is important that they feel there are no difficulties, complications or inconveniences in doing so. Taking the drugs can be seen as the first step in adhering to a medication regimen and as long as there are no problems with taking the drugs, individuals may be happy to take them consistently even if they are not convinced about their efficacy. This findings support those of Morse et al (1991) and Muma et al (1995) who found that individuals that did not adhere to their medication reported more problems with taking the drugs and found the drug regimens very inconvenient.

However, it seems that this is not true for adherence to time requirements. For individuals to attend to the additional requirement of taking the drugs at the right time it is important that they share a high conviction in the benefits of this requirement. Adherence to taking the drugs at the right time may be seen as requiring additional levels of effort and commitment and it could therefore be argued that a strong belief in the benefits of taking the drugs as prescribed is required before individuals commit themselves to such a requirement.

The predictive power of the cues to action construct was also supported by the present findings. The results indicated that those individuals that reported using strategies to remember to take their drugs were more likely to take the correct dose of each drug. The findings are in line with Samet et al (1992) results, who reported associations between cues or reminders and greater adherence to medication. However, cues-to-action were not found to be significant in predicting overall adherence levels and adherence to the time requirements. This can reflect biases in

the item development for this construct since most items were related to strategies regarding remembering to take the drugs. Moreover, the item that asked about the use of pagers was found to have low inter-item reliability and was therefore excluded from analysis. In fact, operationalising and analysing the cues-to-action construct proved to be a difficult task. As Strecher and Rosenstock (1997) pointed out items representing cues to action are often unrelated to one another and tend to show low inter-item correlations. As a result, analysis of aggregated items measuring cues-to-action may not render as much relevant information as the analysis of single items. The development thus and inclusion of more items that specifically address strategies for helping to keep up with the time and dietary instructions alongside analysing them as single items could produce more meaningful findings. It could then be possible to observe effects of cues-to-action to adherence with other aspects of medication taking such as time and dietary requirements.

So overall, the present findings are in line with previous findings supporting the predictive power of barriers, benefits and cues-to-action on adherence with combination therapies (Morse et al, 1991; Muma et al, 1995;). However, having explored the effects of the HBM constructs for each of the three adherence measures, it has allowed us to refine the findings of previous studies and relate them to specific aspects of adherence to combination drugs. So, for example the construct of barriers and cues-to-action were found to best predict taking the correct dose of each drug while benefits best predict adherence to taking the drugs at the right time.

Contrary to Rosentsock et al (1988) suggestion that the addition of the self-efficacy construct to the HBM will increase the models' explanatory power, the findings of

the present study indicated no significant effects of self-efficacy on adherence measures. That is, the results failed to show that individuals' belief in their ability to take their drugs as prescribed could predict whether they were taking their medication or not and whether they were adhering to the medication requirements. Moreover, it is difficult to relate these findings to previous research since most studies adherence to anti-HIV therapies have failed to acknowledge the construct and systematically explore its effects on adherence.

Despite the lack of evidence for the predictive power of self-efficacy, the present findings indicated that self-efficacy was strongly associated with adherence measures. Thus a relationship between self-efficacy and adherence to combination therapies was indicated. The lack of results to support the predictive power of the self-efficacy could be attributed first of all to the sample size of the present study. That is, with larger samples it is possible that more significant results could have been revealed that would have highlighted the role of self-efficacy as a predictor of adherence. Another explanation for the present findings in regards to self-efficacy comes from Warwick, Terry and Gallois (1993) who argued that self-efficacy may mediate the effects of health beliefs on behaviour. That is it is possible that the function of self-efficacy is best understood as a variable that could account for the relationship between health beliefs and adherence. This is indeed a hypothesis that needs further experimental manipulation.

Finally, severity and susceptibility were found to neither predict nor be associated with adherence measures. These findings are in contrast to the HBM assumptions regarding the explanatory power of severity and susceptibility for outcome behavior

and to research findings that have provided evidence for such assumptions (Harrison et al, 1992). On the other hand, there are also research findings that have shown that these two HBM constructs hold little value in explaining adherence to anti-HIV drugs and the present results are thus more in line with these findings (Catt et al, 1995; Muma et al, 1995). It has been argued that the construct of severity may have low utility when applied to severe illnesses such as HIV. For example, Rimer (1998) in his critique of the HBM explained that severity has been shown to have low predictive value in several research findings and thus constructs such as these are still not well understood.

The HBM failed to predict adherence to following dietary instruction. That is, after controlling for depression the HBM constructs did not significantly distinguish those who followed instructions regarding taking the drugs with food or on an empty stomach and those that did not. These findings can not be compared to previous findings since studies into adherence to combination drugs hardly ever acknowledge the importance of keeping up with dietary instructions. However, the present findings suggest that individuals' beliefs about the severity and susceptibility to HIV, alongside beliefs about costs and benefits of the combination drugs did not seem to predict adherence to dietary instructions. Equally, individuals levels of confidence to take their medication as prescribed and their use of strategies to help them remember did not seem to have an effect on participants ability to follow dietary requirements. It may indeed be the case that cognitions regarding illness and medication may not have great relevance to whether individuals take their drugs with or without the right food. The fact for example that depression was found to be strongly associated with adherence to dietary instructions may indicate that

emotional rather than cognitive factors are at the heart of non-adherence to dietary requirements. As Conner and Norman (1998) argued social cognition models such as the HBM are unlikely to provide considerable predictive power in situations where emotional factors are involved. The need for research to clarify the influence of such factors is indicated before conclusive arguments can be drawn regarding the relative importance of the HBM constructs in predicting adherence to the dietary instructions of combination therapies.

Comparing the original and revised models.

In reviewing the HBM constructs Strecher and Rosenstock (1997) argued that more work is needed to specify and measure factors that need to be added to the model to increase its predictive power. They went on to suggest that both self-efficacy and cues-to-action are two variables that could add to the explanatory power of the model. However, in testing this hypothesis the findings of the present study indicated that self-efficacy and cues-to-action did not significantly account for greater variance in the adherence measures compared with the variance accounted by the other four constructs of the model alone. That is, neither of these two constructs added to the predictive power of the model. However, the fact that both constructs were associated with measures of adherence in the present study, serve to underline that many of the arguments presented above regarding the effects of these constructs on adherence could also be applied to explain these findings. So for example, if the suggestion that self-efficacy may mediate the effects of health beliefs on adherence is supported by further research evidence it could serve to explain why self-efficacy was not found to have predictive power. In addition it would suggest that self-efficacy still needs to be retained in the HBM as an important contributing factor.

Similarly, if more representative items measuring cues-to-action were to be developed and if these items were to be analysed as single items the predictive power of cues-to-action as Stretcher and Rosenstock (1997) suggested could be confirmed.

Severity as a moderating factor

In an attempt to describe the HBM in an interactive form, Strecher and Rosenstock (1997) suggested that for susceptibility and indeed for the other constructs of the HBM to be predictive of adherence severity must be high. That is, it was assumed that severity could act as a moderator factor influencing the effect of the HBM constructs on adherence. However, the present findings failed to provide support for Strecher and Rosenstock hypotheses.

This is however not surprising since neither of the concepts were found to be associated with adherence measures. As it was argued above several research findings have demonstrated the low utility of severity and susceptibility with adherence. It is possible therefore that hypotheses regarding the moderating effects of severity may apply in other health-related behaviours but might not be relevant to adherence to combination therapies. Further research is indicated to confirm the relevance of Strecher and Rosenstock hypotheses to adherence with combination therapies.

The effects of ethnicity on adherence

The lack of significant differences in adherence levels between the black and white participants found in the present study are in contrast to previous findings indicating that black individuals tend to show lower levels of adherence to anti-HIV drugs (Singh et al, 1996; Anderson and Weatherburn, 1998a). However, it is important to note that studies that have found relationships between ethnicity and adherence to medication have relied on relatively small size samples of black participants. For example, only 9% of the sample employed by Anderson and Weatherburn (1998a) were black. Therefore, such differences need to be considered cautiously.

In a review of the challenges of minority recruitment in clinical trials for AIDS, El-Sadr and Capps (1992) argued that studies with unrepresentative sample of black participants have led to misleading findings regarding the importance and usefulness of treatment regimens with these populations. They went on to explain that the under-representation of minorities among participants in HIV research is of serious concern and of ethical, social and scientific importance. They concluded that the absence of a segment of the population with specific ethnic characteristics from initial research may prevent scientists from detecting meaningful differences in response to treatments. Although their arguments were specifically addressing under-representation of black individuals in drugs trials, their views are also relevant to research initiatives in other areas of HIV care such as adherence to combination drugs.

Compared to the studies that have explored ethnic differences in adherence to anti-HIV drugs, the present study had a much larger sample of black participants (45%). The fact that differences were not found between black and white participants could indicate that with larger samples the reported differences cease to be significant.

An alternative explanation for the absence of differences in our participants can be attributed to sample biases. That is, the participants in the present study were recruited primarily from an HIV-outpatient clinic and from agencies geared to provide services to individuals with HIV and AIDS. It is possible that the black participants in the current study represent the part of the ethnic population that are more likely to take their medication as prescribed since they were the ones attending the clinic regularly and making contact with organisations that provide support to those on treatments.

Variables associated with adherence

A number of demographic variables were found to be associated with adherence such as language and residential status. In addition associations between depression and time and dietary requirements were also revealed.

Although it was not the focus of the present study to explore these variables and how they relate to adherence nevertheless it is worth reporting on these findings since they are in line with the findings of previous research outcomes (Burack et al, 1993; Joshi, 1998). For example Joshi (1998) argued that unfamiliarity with the English language and socio-economic difficulties could lead to difficulties with adherence to medication among individuals from ethnic minorities. In relating these findings to

the fact that ethnicity was not significantly associated with adherence measures in this study, it would seem that factors related to ethnicity such as language and residential status could be better indicators of differences in adherence than ethnicity per se. Moreover, Singh et al (1996) found that depression predicted non-adherence in their study sample.

Sexuality was also found to have an effect on individuals' taking of their medication. Specifically, it was found that gay individuals were more likely to take the correct dose of their drugs than heterosexual. Unlike previous studies that have concentrated primarily on populations of gay men (Catt et al 1995), the present study did not have that exclusion criteria and therefore differences were evident in terms of sexuality and adherence. Research initiatives today has not as yet explicitly investigated differences in adherence between gay and heterosexual populations. What tends to happen is that gay populations are contrasted to heterosexual populations which in most cases tend to be minorities groups such as black individuals (Anderson and Weatherburn, 1998a).

The presence and influence of many of the above variables on adherence was also reported and discussed by the participants in the focus group as presented in the section that follows.

4.3 EXPLORING BLACK PARTICIPANTS VIEWS AND BELIEFS REGARDING COMBINATION TREATMENTS: DISCUSSING THE RESULTS OF THE QUALITATIVE STUDY

It is with a word of caution that the results of the qualitative study are discussed and this relates to the purpose and nature of qualitative research methodology. As Krueger (1988) argues by using qualitative methods, the researcher gains an understanding of the topic under study by attending to the participants' discussion rather than by testing or confirming hypothesis or theory. In line therefore with Krueger's argument, the purpose of the focus group in the present study was not to broadly generalise the results to all black users of combination therapies, but rather to explore black participants' experiences of taking the anti-HIV drugs. Moreover, participants views regarding the factors that may explain the low levels of adherence among black individuals as reported in the literature were recorded (Singh et al, 1996; Anderson and Weatherburn, 1998).

4.3.1 Discussing the summary findings of the qualitative study

A thematic analysis of participants responses to the questions of the focus group interview revealed a number of themes pertinent to the black participants' experiences with anti-HIV treatments.

Experiences of adherence to combination therapies

In terms of adherence to the combination therapies, all of the participants reported consistently taking combination drugs and having direct experience regarding living with the drugs. The “fear of death” theme was identified early on in the interview as an important factor in participants’ decision to take combination therapies. That is participants shared the belief that HIV and AIDS is a serious illness and thus taking combination therapies was of immense importance in the management of symptoms of ill health. Furthermore, it was acknowledged by the majority of the participants that combination therapies’ power lies in their ability to extend and improve quality of life, till medical advances can treat the virus. So, for many of the participants adherence to combination therapies was a hope for life. However, a range of side effects and difficulties regarding the treatment regimens were also identified and participants acknowledged their effects on taking their drugs as prescribed.

Although the questions generated for the focus group interview did not aim to relate participants views to HBM constructs, nevertheless the themes described above seem to relate to great extent to these constructs. That is, participants believed in the severity of HIV and AIDS, felt that they were susceptible to becoming ill unless they took combination therapies and were able to identify a number of benefits and barriers regarding taking their medication. Therefore, it can be argued that the findings seem to tap into the HBM constructs as described by Rosenstock et al (1994). Moreover, they also seem to be in support of previous research findings relating the importance of the HBM to health behaviours regarding taking combination drugs (Harrison et al, 1992). It can therefore be suggested that the HBM

concepts could also be relevant in understanding adherence issues in black individuals.

However, when participants were specifically asked about their views regarding the low levels of adherence to combination therapies reported among black individuals, a range of themes emerged that related to the participants, socio-economic circumstances.

Factors affecting non-adherence in black users of combination therapies

The fear of stigmatisation and rejection strongly prevailed in participants' responses and was described as a major factor in non-adherence to combination drugs. Participants explained that fear that others may find out that they were HIV positive prevented them from openly taking their drugs when and as required. This finding was also reported by Anderson and Weatherburn (1998a) in their study of the impact of combination therapy on the lives of people with HIV. They explained that despite the considerable impact of HIV on African communities an HIV diagnosis can be a stigmatising experience bringing shame upon an individual and as a consequence an HIV diagnosis is kept secret even from close friends and family.

In addition to fear of stigmatisation, participants referred to issues relating to their residential status as refugees or asylum seekers. The stresses that are associated with an uncertain residential status were particularly highlighted alongside the housing and economic consequences which meant that participants lacked both the private time and space that could facilitate medication taking. These stresses have also been emphasised in a briefing on the Immigration and Asylum Act 1999 produced by the

Refugee Council (2000). In this briefing it is reported that asylum seekers experience many difficulties such as poverty, poor housing, poor access to healthcare and lack of training and employment. Moreover, Anderson and Weatherburn (1998a) reported that many of the African men and women that they interviewed were facing problems regarding their status as immigrants such as Home Office threats of deportation and refusal of benefits. It has therefore been widely acknowledged that individuals' residential status can provide additional stress. For example it has been reported that stress is usually lower when immigration is voluntary and when there is a functioning social support group i.e. an ethnic community willing to assist during the settlement process (Berry, 1992).

It is interesting to note that residential status was also found to be associated with adherence levels in the quantitative study conducted by the author of the present research. The findings indicated that those who were not UK residents showed lower levels of overall adherence and in particular they were found to be less adherent to taking the correct dose of each drug.

El-Sadr and Capps (1992) explained that minority patients have many needs and these often impede their ability to adhere to difficult treatments. They reviewed a number of studies that had recruited participants from minority groups. Their findings indicated that many of those were asylum seekers, or women with young children that needed to be looked after. Moreover most had limited income and lack of resources for associated transportation, food and support with child care. They went on to argue that successful adherence depends on more than just providing the drugs and encouraging their use and taking as prescribed. For most of these patients

their socio-economic circumstances were major obstacles in prioritising their health and the taking of their drugs as required.

Another theme that emerged in response to factors affecting adherence to combination therapies in black individuals related to participants non-regimental attitudes to life. The majority of the participants agreed that black Africans tend to have a more laid-back attitude towards everyday living tasks and this includes taking medication. Participants therefore expressed great scepticism regarding the suitability of the drugs with African users and questioned how well they fit with their non-regimental ways of living. So alongside socio-economic factors, culturally defined attitudes and behaviours also played an important role in the participants' experiences of non-adherence to combination therapies.

It could be argued that the issues raised by the participants regarding the difficulties in adhering to anti-HIV treatments could have an important role to play in shaping their health beliefs. So, although it was suggested earlier that the HBM constructs may be useful in understanding adherence to combination therapies in black users of the drugs, these constructs need to be explored and considered within the wider socio-economic and political context that black individuals experience daily. As Joshi (1998) argued these are all important issues to consider when studying adherence levels among individuals from different cultural and ethnic backgrounds.

Strategies and support systems for black users of combination therapies

The effects of the socio-economic circumstances were also evident on the strategies that participants employed to remember to take their drugs. That is, participants had to primarily rely on their memory since the use of any reminders such as alarms or pillboxes would be making their medication taking noticeable by others. Moreover, the fact that very few would have disclosed their status to friends and family members made it impossible that others could act as source of support and encouragement in adhering to combination drugs. As Anderson and Weatherburn (1998a) explained when HIV diagnosis can not be discussed with ease, support may be hard to access.

In light of the lack of appropriate support for black Africans, participants identified a clear need for more accessible information regarding HIV and treatments and most importantly a need for an improved doctor-patient relationship. It was felt for example that participants' clinicians were not always aware of agencies that could provide support and information to African people and it was argued that clinicians needed to be more in touch with services at a community level. In fact, the importance of the patient's interaction with the health professional has been frequently highlighted in the literature (Weishut, 1996; Horne, 1998). The clinician was therefore identified as an important source not only of information about participants' health and medication but also as an important link with support systems in the community.

For the participants in the present study, peer support groups were reported as an important source of help with dealing with the difficulties and anxieties regarding the illness and the taking of medication. Formal HIV support networks for African communities have indeed been described as invaluable not only because of the services they provide but most importantly because of their willingness to accept and value the experiences of African people with HIV (Anderson and Weatherburn, 1998a).

In terms of participants' suggestions for available information regarding the combination therapies and their implications, the answer has been provided by the Terrence Higgins Trust, a national voluntary organisation providing information and support services to individuals with HIV and AIDS. The trust has produced a booklet titled "An introduction to HIV treatments for African people". This booklet is written for black African people affected by HIV and aims to provide help with making informed choices about treatments. It also includes information regarding support services and information centres for African people. This booklet has been in existence for 2 to 3 years. The fact that the participants in the focus group did not refer to it may serve to illustrate their argument regarding the lack of appropriate links between professional settings and community agencies.

Contrasting the African and Gay community context.

Participants' socio-economic circumstances were also referred to as a measure of contrast between gay and black users of combination therapies. That is, the focus group participants saw their experiences of HIV and combination therapies as widely distinct from those of gay or other white users of the drugs.

Although themes such as “the fear of stigmatisation and rejection” were not seen as exclusively descriptive of the African community they were nevertheless perceived as having a much greater impact on the lives of African users of combination therapies. Participants for example felt that gay individuals on combination therapies talk more openly about their illness and they are not as secretive about taking medication in public if necessary.

In fact, similar differences in responses to HIV and medication have also been reported by Anderson and Weatherburn (1998a). The authors reported that there is indeed a widespread acceptance of the HIV reality among the gay community and as a result the gay culture has provided the context where it is both possible and acceptable to learn about HIV. So, there are extensive opportunities not only for finding out about HIV and its effects but also for accessing support in dealing with its personal impact. However, unlike gay individuals, Africans diagnosed with HIV are unlikely to turn automatically to their community to find the support and resources that may need to deal with their illness. As a result, it was argued that for many Africans the devastation of an HIV diagnosis is compounded by an anxiety about others knowing their diagnosis and a lack of adequate knowledge about treatment options.

Although the above arguments and discussion points serve to indicate that differences may indeed exist between the gay and African communities, at the same time these findings need to be considered very cautiously. Members of different communities may share a range of specific beliefs, attitudes and knowledge about

health and medication. However, much diversity is also usually evident within communities and therefore the present discussion points can not be seen as describing the cultural differences between the gay and African communities. They only serve to communicate the feelings of a small group of black users of combination therapies regarding their experiences of living with HIV. This is also true for all the themes reported in this section.

Therefore, although the main findings of the qualitative study have provided useful insights regarding the black participants' experiences of combination therapies, they are nevertheless far from being conclusive regarding the issues that the study aimed to address since they are only based on the findings of one focus group. Thus, the findings need to be further substantiated by additional research before firm conclusions can be drawn regarding the experiences of black users of combination therapies.

4.4 IMPLICATIONS FOR CLINICAL PRACTICE

In presenting and discussing the findings of the quantitative and qualitative parts of the present research study, a range of clinical implications were identified. These would be summarised and more extensively discussed in the present section.

The present findings indicated that different levels of adherence were evident for different requirements of the combination therapies. That is, higher levels of adherence were reported for taking the correct doses of each drug in comparison to

adherence levels to time and dietary requirements. Thus, it seems that asking individuals to report on their adherence levels to each aspect of their treatment can render different adherence levels. The current findings therefore serve to indicate the importance of utilising adherence measures to combination therapies that reflect the complexity involved in taking these drugs. They also serve to highlight the necessity for practitioners to inquire not only about their patients' consistent taking of the drugs but also about their adherence to the time and dietary instructions. Only then researchers and clinicians can start building a representative picture of the difficulties that individuals face regarding taking their medication as prescribed. This is particularly important since successful management of the HIV virus requires high level of adherence to all the treatment requirements. Thus, by identifying problems with specific aspects of the treatment interventions can be designed that are geared to address the specific drug requirements so that the required levels for successful therapeutic outcome can be achieved. This argument was also supported by comments from conference participants to the presentation of the above findings at an annual conference (Papadopoulou and Shaw, 2000).

In terms of testing the HBM, the findings of the present study have provided limited but nevertheless important evidence for the relevance of health beliefs in adherence to combination therapies. The predictive effects of benefits, barriers and cues to action on adherence indicated in this study highlight the importance of these concepts in the taking of combination drugs. An understanding of the long term benefits of the drugs coupled with beliefs that the benefits of taking the drugs outweigh their costs and difficulties was shown to be important determinants of drug

taking behaviours. Moreover, cues to action were also found to predict the consistent taking of medication.

With these findings in mind, a need is indicated for clinicians to explore and consider their patients' beliefs regarding the effects of combination treatments on their health right from the start of their contact with them. Are the patients aware of the long term health benefits of the combination treatments? Do patients anticipate or indeed experience any difficulties taking the drugs as prescribed? Do they employ strategies to help them remember take their medication? These are all key questions that need to be addressed in assessing patients progress with the medication and most importantly in implementing intervention programs to address non-adherence. Moreover, the answers to these questions need to be regularly revised at follow-up meetings between the doctor and the patient, so that difficulties can be identified at an early stage and adequate solutions found.

For the above to apply and happen, consultation time may need to be extended to allow for doctors to ask these questions and for patients to have the time to articulate their difficulties. It is also possible that the involvement of other professionals such as nurses, HIV counsellors or even clinical psychologists is requested in supporting and facilitating the exploration of adherence difficulties. Moreover, clinicians need to possess the necessary problem-solving skills to effectively negotiate solutions to the difficulties their patients may face. There may be for example a need for doctors to tailor the treatment regimens to fit their patients pattern of behaviour or to introduce mechanical aids such as timers to deal with mechanical barriers such as forgetting when to take the medication (Ley, 1997). It is only then that a

collaborative clinician-patient relationship can be established, difficulties can be resolved and adherence can be improved.

It is of course possible that newer drugs or less rigorous regimens may develop as the effects of the drugs are better understood and the present findings support the urgency of such new developments in order that barriers to taking combination therapies are minimised. Meanwhile, and in light of the focus group participants' responses regarding the importance of adequate information in treatment decision making, efforts must be concentrated in ensuring that users of the drugs are constantly updated with news regarding the benefits and difficulties of the treatments.

The above discussion points are particularly relevant to black African patients. Although the findings of the present study did not indicate significant differences between the black and white participants, it is nevertheless important to note the suggestions offered by the focus group participants regarding the need for links with community agencies as a source of information and support. The need for a wide-ranging, thorough and continuing education project at community level has also been acknowledged by Bhatt (1997). He went on to explain that educational projects also need to be complemented with good quality health advice and counselling at the treatment centres.

Moreover, initiatives such as the above are urgently required in order to provide the context in which the socio-economic and political circumstances faced by groups with difficulties with adherence can be widely acknowledged and addressed. So for

example, issues around fear of stigmatisation and rejection among African communities need to be dealt with by intervention initiatives at a community and societal level, although changes in knowledge and beliefs will surely continue to be required for behaviour change at an individual level (Rosenstock et al, 1994). Researchers and clinicians need therefore to be aware of how socio-economic factors affect their patients beliefs and expectations regarding the treatments on offer. Moreover, clinicians should be able to relate these factors to their patients' non-adherent behaviour and feel confident to openly address them in their consultations with them.

Bearing the above arguments in mind, it becomes evident that in planning programs to influence the adherence behaviour of large groups of people the role of HBM constructs must be considered within the context in which they have been developed. As Rosenstock et al (1994) explained permanent changes in behaviour patterns can rarely be brought about solely by direct attacks on belief systems. Therefore the effectiveness of intervention programs will very much depend on the extent that difficulties with adherence have been addressed both at an individual as well as at a societal level.

4.5 LIMITATIONS OF PRESENT STUDY AND RECOMMENDATIONS FOR FUTURE RESEARCH

The present study was designed to investigate adherence to combination therapies using the HBM and moreover to explore the experiences of black individuals on

combination treatments. The findings however, need to be considered within the context of the study's limitations and shortfalls and it is to these that we now turn.

The present study was a cross-sectional study measuring individuals' adherence to combination drugs over the period of a week. Although, it has been argued that this time frame is a more reliable way of gathering information regarding adherence than using longer time periods, nevertheless the present findings can not be generalised to adherence to medication over longer periods of time. In light of this limitation longitudinal studies could potentially provide important contributions to our understanding of adherence over long periods of time. This is particularly important when exploring and trying to understand adherence to medication that needs to be taken consistently for life as in the case of anti-HIV treatments. In fact, Rosenstock et al (1994) reviewed both cross-sectional and longitudinal studies that had used HBM constructs to predict health-related behaviour and went on to recognise the clear superiority of longitudinal designs in studies of belief-behaviour relationships. Thus, further studies using prospective longitudinal designs are indicated to test the relevance of the HBM constructs in predicting adherence to combination therapies over long periods of time.

It should be also noted that the present findings represent a somewhat limited picture of adherence issues to combination therapies since they mostly reflect the responses of individuals who have managed to take the drugs, attend HIV clinics regularly and join supportive environments such as the local agencies approached in this study. However, when studying non-adherence behaviour it is also important that the experiences of people who have not benefited from combination therapies are

considered. Their views and health beliefs could offer important insights into the difficulties related to adherence to combination treatments. It could therefore be argued that to some extent sample biases were evident in the present study and this needs to be rectified in future research initiatives by ensuring the representative sampling of individuals with a range of experiences of combination therapies. It is only then that conclusive arguments can be drawn regarding non-adherence to anti-HIV treatments. Keeping with the theme of sampling, the lack of significant results regarding the predictive effects of susceptibility, severity and self-efficacy on adherence could be attributed to the size of the sample. That is with a larger sample possible effects could have been evident and thus additional research evidence is needed to substantiate the present findings before conclusions can be formed regarding the relevance of these constructs on adherence to combination therapies.

The HBM questionnaire used in the present study was specifically designed to test the research hypotheses under consideration. Like any newly developed questionnaire validity and reliability indications were collected. The procedures used by Champion (1984) in the development of a HBM questionnaire regarding breast self-examination were employed. However, since the objective of the present study was not the development of a tool for use in predicting adherence to combination drugs, only the necessary analysis and check ups were carried out to ensure the appropriateness of the HBM scale for use in the present study. Further item development and analysis is required if the present HBM questionnaire is to be utilised more extensively in future research studies. In particular the reliability analysis of the scale indicated that further item development on the severity and cues to action constructs should be conducted in order to improve their reliability levels.

Moreover, the construct validity of the scale needs to be determined - that refers to the extent to which the scale measures the constructs that is designed to measure. Thus, by factor analysing all the of the scale scores, individual items could be sorted into groupings or factors on the basis of correlations between these items. The results of factor analysis can indicate whether items are loaded on the factors (HBM constructs) they are supposed to be (Sheeran and Abraham, 1998). It is only then that satisfactory construct validity can be demonstrated.

In terms of testing the HBM, the present study was also set up to explore Rosenstock's hypothesis that the construct of severity can act as a moderating factor in the relationship between health beliefs and adherence measures. Although the present findings failed to provide supportive evidence for this hypothesis, the findings nevertheless indicated that it is possible that other HBM constructs can also be conceptualised in interactional terms. So, for example contrary to the HBM predictions and previous research findings self-efficacy was not found to predict adherence levels in the present study. However, the fact that associations between self-efficacy and adherence were showed, may serve to point out that it is possible that self-efficacy may mediate the effects of health beliefs on adherence. Indeed further conceptualisation of the HBM constructs in terms mediating and moderating relationships could prove to be a more constructive way of understanding the influence of health beliefs on adherence and one that could prove to increase the predictive power of the HBM. It remains therefore for future research initiatives to systematically explore such relationships and establish their interactive effects on adherence.

Finally, the present study aimed to conduct a number of focus groups with black users of combination therapies. Unfortunately, recruiting for the groups was not easy and as a result only one group was conducted. Therefore the findings derived regarding black participants experiences of combination therapies are far from conclusive and need to be supported by additional findings from similar groups. However, the experience of recruiting for the groups raised a number of questions regarding the appropriateness of group based methodologies in studying behaviour patterns and especially adherence to medication in African communities.

The challenge of minority recruitment in AIDS related research has been extensively discussed by El-Sadr and Capps (1992). They argued that efforts to extend clinical research trials to minority communities suggest that a new paradigm is required to make such efforts succeed. This paradigm must reflect the special needs of these communities and should recognise historical mistrust of clinical trials and the need for extensive educational and social support services. Although their discussion points were related to participation of African individuals in drug trials, their arguments can be relevant in other areas of clinical research with this population. The authors went on to explain for example that traditionally the recruitment of a patient for a research study involves primarily the provision of information regarding the specifics of the study prior to obtaining informed consent. However, for patients who have no previous experience of group discussions regarding their medication taking, participating in a focus group would seem a daunting experience. In these cases successful recruitment requires an extensive educational effort, to ensure that the participants have a clear understanding of the purposes of the study, the nature of the groups conducted and the issues that need addressing. This is however a time

consuming process that requires educational skills, patience and the building of trust (El-Sadr and Capps, 1992). Moreover, it requires a great amount of liaising with community based agencies that offer services to African communities.

The time constraints of the present study did not permit the application of all the above strategies in recruiting for the focus groups. Therefore, research initiatives that wish to use focus groups need to be aware of the above difficulties and take the above suggestions into consideration in order to ensure successful recruiting from African communities. Moreover, the issues raised by the focus group could be used to construct questionnaires and measures of adherence with combination therapies for black populations for use in further qualitative and quantitative research in the field.

4.6 CONCLUDING REMARKS

Adhering to combination therapies for HIV and AIDS is a complex task, which requires substantial effort on the part of the individuals receiving these treatments.

Non-adherence on the other hand has not only shown to have been personal consequences but also economic and public health consequences. The understanding of non-adherence has thus attracted a wealth of research and clinical interest.

Theoretical models such as the HBM have been consistently used over the last years in research into adherence in an attempt to investigate the factors that could account for non-adherent behaviour. The findings today have been primarily based on cross-

sectional studies and are far from being conclusive. So, an assessment of the patients' beliefs of the benefits and costs of medication alongside an exploration of the reminders that patients use have all been shown to be significant factors in predicting adherence to combination therapies. However, the role of concepts such as severity and susceptibility to HIV is still unclear and in need of further systematic investigation. Furthermore the effects of self-efficacy on adherence were also found to require the support of additional research evidence. Most importantly the present findings need to be substantiated by results from longitudinal studies.

The implications of these findings however are broad and wide-ranging. It was argued in the present study that although awareness of the above predictive factors is an important contribution to the ways that clinicians address adherence difficulties in consultations with their patients, these factors should not be considered and used outside their context. That is, an awareness of the specific socio-economic circumstances that individuals in need of medication are faced with is also important and of great relevance to the development of community based intervention programs. The findings regarding the relevance of patients' socio-economic circumstances on adherence suggest that further follow up studies are indicated for enriching our understanding of adherence in general and as it relates to specific ethnic groups. The findings of the focus group can indeed act as useful pointers for developing research protocols for a more extensive exploration of the issues that have been raised in this study.

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APPENDICES

APPENDIX 1

Ethical Approval Letter



Chairman: Brian Blackler
Chief Executive: Christine Outram

Ref: KB/CH

15 March 1999

Liz Shaw
Chartered Clinical Psychologist
Haringey Healthcare NHS Trust
St Ann's Hospital

Dear Ms Shaw

526 - Adherence to combination therapy in people with HIV/AIDs

I write to inform you that the amendments to the above study contained in your letter (undated) have been approved.

The Committee look forward to receiving a copy of your interim report in six months time or at the end of your project if this is sooner.

Yours sincerely

Mrs L H Lipson
Chair
Enfield & Haringey LREC

Please reply to:

APPENDIX 2

Demographic Data Form

DEMOGRAPHIC INFORMATION

Please give the following confidential details about yourself by writing on the lines below or ticking the appropriate boxes:

AGE: SEX: RELIGION:.....

HIGHEST EDUCATIONAL QUALIFICATION:
(British or Other)

OCCUPATION: Employed ☐ Unemployed..... ☐ Student..... ☐

Current or most recent occupation:

ETHNIC ORIGIN (Please tick as appropriate):

White U.K ☐ Black/African ☐ Asian ... ☐ Black U.K ... ☐

Black/Caribbean... ☐ White -European ... ☐ Other

RELATIONSHIP STATUS (Please tick as appropriate):

Single ☐ In a relationship -living together ☐

Married ☐ In a relationship -not living together ☐

Divorced ☐

SEXUALITY (Please tick as appropriate):

Heterosexual ☐ Gay ☐ Bisexual ☐

LIVING ARRANGEMENTS: Do you live alone? YES..... ☐ NO..... ☐

If NO do you live with (you can tick more than one boxes):

Parents... ☐ Partner/Spouse... ☐ Relatives ... ☐ Own family ... ☐

Friends ... ☐ Others ... ☐

Do you have a room for your own use? Yes..... ☐ No..... ☐

LANGUAGE: Is English your first language? YES.... ☐ NO ☐

If NO, how good is it?

Very Good ... ☐ Good... ☐ Not Good... ☐

RECREATIONAL DRUGS EXPERIENCES:

Have you ever taken recreational drugs? YES ☐ NO... ☐

If YES, have you ever injected drugs? YES ☐ NO... ☐

(Please feel free NOT to answer the following question)

RESIDENTIAL STATUS (Please tick as appropriate):

U.K National ... ☐ Student Visa ☐ Work Visa ... ☐

Other Visa ... ☐ Asylum seeker .. ☐ Other

APPENDIX 3

Health Belief Model Questionnaire

Health Belief Model Questionnaire

Below are a number of statements regarding peoples' beliefs concerning combination drugs. Read each statement carefully and then show to what extent you agree or disagree with it by ticking the appropriate box. Please note that there are no right or wrong answers.

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1. A good relationship with my doctor/nurse has been a motivating factor in keeping up with the medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I believe they will find a cure before I ever suffer severe complications due to HIV/AIDS.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I feel that combination drugs help overcome the tiredness associated with having HIV/AIDS.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I believe that my chances of developing severe complications due to HIV are low.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I have the ability to take my medication even though it interferes with my social life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My friend/partner/family member reminds me when to take my medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If I do not take combination drugs I will not be able to fight complications due to HIV on my own.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I believe the risk of death due to HIV/AIDS is not high.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I think I would be more closely monitored at the clinic if I take combination drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I believe HIV/AIDS can be overcome just like any other illness.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. If I take combination drugs I am less likely to get ill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
12. The thought of having to cope with being ill from the side effects of the drugs puts me off combination therapy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. HIV/AIDS is just another chronic illness.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I think combination drugs can buy me time while a cure is developed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I don't think the side effects of the combination drugs are dangerous to my health.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I use a number of strategies so I don't miss my doses.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I am generally a lucky person and therefore feel that good health will be on my side.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I will do better if I start combination drugs before I become ill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. The possible side-effects from taking combination drugs outweigh their benefits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I don't think HIV/AIDS is a hopeless disease.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. The doctors do not really know what the drug are really doing to me (I feel like a guinea pig).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I worry that taking combination drugs may affect my sex life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Reading good reports about combination drugs has encouraged me to take my medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. If I am taking combination drugs now it will cease to be effective when my body really needs help.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
25. Taking combination therapy makes me feel that an AIDS diagnosis is on the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Taking combination drugs interferes with my daily routines.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I eat a good diet and look after myself so I am unlikely to get ill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. I am afraid that others will be able to tell I have HIV/AIDS because of the side effects of the combination drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. It is easy for me to take the combination drugs that I was prescribed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I don't feel confident that I would remember to take my medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. I think that AIDS is more serious than any other disease.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Taking combination drugs has disrupted my social life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. I am confident that I can overcome any difficulties I have with taking combination drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. The possible nasty side effects associated with combination drugs reduce my incentive to take them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. I don't want others to know that I am on combination drugs and this puts me off taking them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. I do not think that AIDS is a terminal illness anymore.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
37. Despite the side effects of taking combination drugs, I feel that I am able to stick to the medication prescribed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. I hold strong religious/spiritual beliefs which I feel can help me overcome HIV/AIDS without taking combination drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. I worry that taking combination drugs may affect my ability to have children.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. I am a very resilient person and will fight against becoming ill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. I use pagers/pill boxes to help me remember when to take my medication.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Taking combination drugs will help reduce worries that I have about my future health.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Others are more likely to develop AIDS before I do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. The side effects of the combination drugs interfere with my ability to care for others (children, partner, parents e.t.c.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. My friends have advised me to take combination drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX 4

Adherence to Combination Therapies Questionnaire

Drug Information Sheet

1. What year did you first start taking anti-HIV therapy?

.....
.....

2. How many times have you modified or changed any of your combination drugs?
(tick one box)

Never changed or modified drugs... <input type="checkbox"/>	Four to five times <input type="checkbox"/>
Once <input type="checkbox"/>	Six times or more <input type="checkbox"/>
Two to three times <input type="checkbox"/>	Don't know <input type="checkbox"/>

3. What were the reasons for your most recent drug combination change? (e.g severe side effects, decreasing T-cell count, drugs inconvenient to take, increasing viral load e.t.c.)

.....
.....
.....
.....

4. Do you have enough say in decisions about your anti-HIV treatment ? (tick one box)

All the time <input type="checkbox"/>	Not very often <input type="checkbox"/>
Most of the time <input type="checkbox"/>	Not at all <input type="checkbox"/>
Sometimes <input type="checkbox"/>	Don't know <input type="checkbox"/>

Combination drugs currently taken

1. Which anti-HIV drugs are you currently on ?

Drug Name	Dose	Times per day
.....
.....
.....
.....
.....

2. How many pills/capsules of anti-HIV drugs do you have to take per day?

.....

3. Are you currently on any other medication (besides anti-HIV drugs?)

Yes..... ☐

No..... ☐

If YES, what are you taking and what is it for?

.....
.....
.....

4. What life changes did you have to undergo in order to take combination drugs ? (e.g diet changes or other)

.....
.....
.....

5. Have you got any side-effects from the anti-HIV drugs?

Yes..... ☐

No..... ☐

If YES:

a. What are they?

.....
.....
.....

b. How MUCH do they bother you? (tick one box)

Greatly ☐ Moderately ☐ Not at all ☐

c. How OFTEN do they bother you ? (tick one box)

Every day..... ☐ About every week..... ☐ About every month ☐

About every few months.... ☐ About every few weeks ☐ Never ☐

6. How often do you NOT take your anti-HIV drugs AS PRESCRIBED? (tick one box)

Every day..... ☐ About every week..... ☐ About every month ☐

About every few months.... ☐ About every few weeks ☐ Never... ☐

Other, please specify

7. When was the last time you did NOT take your anti-HIV drugs AS PRESCRIBED?
(tick one box)

Today..... ☐ Yesterday.... ☐ Up to a month ago ☐ Few months ago.... ☐

Up to a week ago ☐ Never.... ☐ Other, please specify

8. If you do NOT take your anti-HIV drugs AS PRESCRIBED does that mean that you (tick as many boxes as apply):

- a. Do not take the drugs at all..... ☐
- b. Take only some of the drugs..... ☐
- c. Take the drugs but not at the right time..... ☐
- d. Take the drugs but not with the right food..... ☐
- e. I always take all the drugs at the right time and in the right way ☐

9. If you MISS a dose is it usually the same one? (i.e lunch dose or weekend dose)

Yes..... ☐ No..... ☐ Never miss a dose ☐

If YES which dose is it?

10. If you DELAY taking a dose is it usually the same one? (i.e lunch dose or weekend dose)

Yes..... ☐ No..... ☐ Never delay taking a dose ☐

If YES which dose is it and how long was the delay?

11. The last few times you did NOT take a dose AS PRESCRIBED, what were the main reasons for missing it? (tick as many as apply)

At work..... ☐ I was asleep..... ☐ Drunk ☐
I was with someone and ☐ Just forgot ☐ Out clubbing... ☐
did not want them to know
Felt ill from side effects..... ☐ Run out off drugs ... ☐ Too tired..... ☐
Felt well and didn't think I need them ☐
Felt well and thought I could have a break from taking them ☐
Other, please specify

12. Do you ever plan to miss a dose/s of anti-HIV drugs?

Yes ☐ No..... ☐

If YES is it because you

Want to drink and you feel combination drugs and drinks do not mix ☐

Want to take recreational drugs but drugs and combination therapy do not mix... ☐

You have guests staying with you and you don't want them to know..... ☐

You are going on holidays..... ☐

Other, please specify

13. Do you discuss with your doctor/nurse when you have NOT taken your anti-HIV drugs at the right time or in the right way ?(tick one box)

Yes..... ☐ No..... ☐

14. How would you rate your relationship with the doctor/nurse that monitors your combination drug treatment?

Very satisfactory..... ☐ Quite satisfactory..... ☐

Neither satisfactory nor unsatisfactory..... ☐

Quite unsatisfactory..... ☐ Very unsatisfactory..... ☐

15. Who or what has been important in helping you remember to take your anti-HIV as prescribed? (tick as many as apply)

Partner ☐ Buddy or carer..... ☐ Treatment diary ☐

Family member ☐ Self reliance/memory... ☐ Pillbox ☐

Friend ☐ Treatment alarm ☐

Other, please specify:

16. Do you think you are getting the support you need to help you take your anti-HIV drugs at the right time, in the right way? (tick one box)

Yes..... ☐ No..... ☐

If NOT what would help you take your anti-HIV drugs as prescribed?

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17. Do you feel uncomfortable taking combination drugs due to:

a. your own religious/spiritual beliefs about HIV/ AIDS and the drugs ?

Yes..... ☐ No ☐

b. the religious/spiritual beliefs of those around you about HIV/ AIDS and the drugs?

Yes..... ☐ No ☐

If YES would you like to tell us a bit more about these beliefs?

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.....

18. How much of the time over the last week were you able to (tick as apply for each question):

	All of the time	Most of the time	Half of the time	Some of the time	None of the time
a. take the correct dose of each drug?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. take your medication at the right time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. follow instructions about whether to take drugs with food or on an empty stomach?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. take the right dose of combination drugs, at the right time and in the right way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. The most important thing about taking combination drugs is: (tick one box)

- To take all the drugs prescribed at the right dosage ☐
- To take the drugs at the right time..... ☐
- To take all the drugs at the right dosage, at the right time and in the right way..... ☐
- To take some of the drugs whenever you remember to ☐
- To follow the dietary instructions around taking the drugs ☐

20. Are you having any complementary/alternative therapy (i.e homeopathy, reflexology, acupuncture, spiritual healing, herbal remedies e.t.c.)?

Yes..... ☐ No ☐

If YES can you tell us a bit about it/them?

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21. Is there anything else that you would like to tell us about your experience of taking combination drugs?

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Thank you for your co-operation !

APPENDIX 5

Information Sheet

HARINGEY

Healthcare NHS Trust

Title: Adherence to combination therapy in people with HIV/AIDS Information Sheet

Dear participant,

We are currently conducting some research into the experiences of people who take combination drug treatments. We know that taking combination drugs is not always easy, and we are hoping that this study will enable us to understand the factors that make it difficult to take these drugs. This understanding may help us find better ways to help people who find it difficult taking their combination drugs.

We would therefore like to invite you to take part in this study, which involves completing some questionnaires. The questionnaires ask about your experiences, feelings and views about HIV/AIDS and combination drugs. These should not take more than 30-45 minutes to fill in.

All the information that is given to us is confidential. You do not have to put your name on the questionnaire and no information about any individual who takes part will be given to professionals or others involved with their care. Only the general findings from the study will be shared with them once it is completed. If you are interested, you can also find out about the outcomes of the study, as a copy of it will be available at the T1 ward reception.

We would also like to invite a small number of participants to take part in a group discussion in order to gain a more in depth understanding of their experiences of combination drug therapies and their views about what makes it difficult to take these drugs. The group discussion will take about one and half hours. The discussion will be tape recorded to guarantee accuracy but your identity will not be disclosed on the tape. The tape will be erased after transcribing.

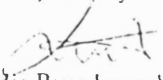
This is a separate part of the study. If you complete the questionnaires it does not mean that you have to participate in such a group discussion. There is a space on the consent form to indicate whether or not you wish to participate in a more detailed discussion of your experiences. Even if you have indicated your wish to participate, you are free to change your mind and withdraw from the study at any time without giving any reason for the withdrawing and without your treatment being affected in any way.


All research proposals using human participants are reviewed by an ethics committee before they can proceed. This study was reviewed by the local research ethics committee of Enfield and Haringey Health Authority.

If you have any further questions about the study do not hesitate to ask the researcher that has approached you with this information sheet or contact Liz Shaw on 0181-4426144.

If you would like to help us with this study, please complete and sign the consent form attached to this page.

Thank you for your time.


Andia Papadopoulos
(Clinical Psychologist in Training)


Liz Shaw
(Chartered Clinical Psychologist)



APPENDIX 6

Consent form



HARINGEY
Healthcare NHS Trust

CONFIDENTIAL

CONSENT FORM FOR PARTICIPANTS

Research project: Adherence to combination therapy in people with HIV/AIDS

Researcher: Andia Papadopoulou, BSc, MSc
Liz Shaw, BSc, MSc

Have you read the information sheet about this study? YES/NO

Have you received enough information about this study? YES/NO

Have you had an opportunity to ask questions and discuss this study? YES/NO

Have you received satisfactory answers to all questions? YES/NO

Do you understand that you are free to withdraw from this study at any time and without giving a reason for withdrawing? YES/NO

Do you agree to take part in this study? YES/NO

Some participants may be asked to join a small group of no more than 8 people to discuss their experiences of taking combination drugs in more detail. The meeting would last for about one and half hours. This meeting would be recorded on audiotape but erased after the details are transcribed to ensure confidentiality. Please tick one of the statements below to indicate whether you would like to participate in this part of the study.

- I do NOT wish to discuss my experiences of taking combination drugs in a group discussion. _____
- I would be happy to join a group discussion and discuss my experiences of taking combination drugs. _____

Name: Tel. No:
(only if you wish to take part in the group discussion)

Signed Date:

Name in block letters:

Researcher's signature:



APPENDIX 7

Focus Group Interview Schedule

ADHERENCE TO COMBINATION DRUGS -FOCUS GROUP

Size of group: 6-8: Number of questions :4-6

THE OPENING QUESTION

1. How long have you been coming here and what is it that you like about coming here (at the Umoja dropping in centre)?

INTRODUCTORY QUESTION:

2. I am here today because I want us to talk about your experiences of taking combination therapies. Can I check if you all have direct experience of being on combination drugs? I would like to start by asking you to tell me what you understand by ‘compliance or adherence to combination drugs’?

Probe:

-If someone is said to not adhere to combination treatments what does that mean?

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TRANSITION QUESTION

3. Now lets talk about your experiences of taking combination drugs. What has made you decide to take combination drugs?

Probes:

- help stay healthy, less likely to get ill
- can buy me time while a cure is developed
- doctors pressure me into taking them
- severity of HIV can't fight it without drugs

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KEY QUESTIONS

4. What would you say the benefits of taking combination therapies are?

Probes:

- help overcome tiredness and other symptoms
- as above

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5. Let's talk about the difficulties of taking the drugs. What will you say some of these difficulties are?

Probes:

- side effects
- interferes with daily routines
- disrupts my social life
- interferes with ability to care for others

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6. What things help you take your drugs as prescribed?

Probes:

- pagers, pill boxes, and diaries
- my friend/partner reminds me to take my medication
- strategies to remember
- good relationship with doctor and nurse
- reading good reports, advice from friend

TRANSITION QUESTION

7. Now , I would like to share with you the findings of research that have pointed out that black users of combination drugs are more likely to be nonadherent than any other ethnic group. What are the reasons that would make black individuals less likely to take combination drugs as prescribed?

Probes:

- Different beliefs about illness, don't think HIV as a serious illness
- Different beliefs about health I.e if you don't have symptoms no need to take drugs
- Different beliefs about treatments I.e western drugs are not good, religion more powerful than drugs.

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KEY QUESTIONS

8. Do you think that black people have different views or ideas about HIV and AIDS than others that make them not adhere to the drugs?

Probes:

- it is not a serious illness
- if I believe enough I will be OK
- if I don't have symptoms then I am not ill.

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9. Do you think that black people have different ideas and beliefs about combination drugs than others that make them not take them as prescribed?

Probes:

- westernised medication does not work
- we are guinea pigs to these drugs
- our medicines work better I,e herbal or others
- if you believe in god you will be o.k.

10. Researchers and doctors are aware of people using traditional remedies along side of instead of western medicine. Do you think black people are more likely to use traditional remedies than western ones? What may these be?

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11. What would be helpful in supporting black clients to take combination drugs as advised?

Probes:

- peer support and groups such as this one
- better doctor/nurses relationships
- more black/ethnic users friendly environments especially in HIV clinics
- more information in native languages

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ENDING QUESTION:

12. From all the reasons (summary) for why black people are less likely to take the drugs that we discussed, which one would you say is the most important to keep in mind?

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SUMMARY QUESTION:

I would like to summarize our conversation

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13. Is this an adequate summary?

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FINAL QUESTION:

14. The purpose of our discussion was to explore your experiences of taking combination drugs and to think of the reasons why studies have shown that black people are less likely to take their drugs as prescribed.

Have we missed anything? Is there anything that we should have talked about but didn't ?

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