

**Racial differences in willingness to participate in
HIV prevention clinical trials amongst university
students in KwaZulu-Natal, South Africa**

Submitted to:

**NELSON R. MANDELA SCHOOL OF MEDICINE
UNIVERSITY OF KWAZULU-NATAL DURBAN
SOUTH AFRICA**

Submitted in partial fulfillment of the academic requirement for the
degree of Master of Public Health (Epidemiology and Biostatistics) in
the School of Family and Public Health Medicine, University of
KwaZulu-Natal

by

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November, 2013

DECLARATION

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ACKNOWLEDGMENTS

First and foremost, I would like to thank God for granting me this blessing.

The assistance of the following institutions and individuals are gratefully acknowledged:

1. The University of KwaZulu-Natal for granting approval to collect data within the university community
2. Professor Douglas Wassenaar for all his guidance, support and assistance
3. Ms. Nonhlanhla Yende and Ms. Lise Werner for statistical guidance
4. Academic and administrative staff of the Department of Public Health
5. My family for their constant motivation, love and support
6. Friends and work colleagues for their motivation and support

ACROYNMS AND ABBREVIATIONS

ANOVA -	Analysis of Variance
ARV -	Anti-Retroviral
CFA -	Confirmatory Factor Analysis
CRIS -	Clinical Research Involvement Scale
DSMB -	Data Safety Monitoring Board
FACTS -	Follow-on African Consortium for Tenofovir Studies
HCT -	HIV Counseling and Testing
HEAIDS -	Higher Education HIV/AIDS Program
HVTN -	HIV Vaccines Trials Network
MCC -	Medicines Control Council
MSM -	Men who have Sex with Men
NHREC -	National Health Research Ethics Committee
NNRTI -	Non-Nucleoside Reverse Transcriptase Inhibitors
PrEP -	Pre-Exposure Prophylaxis
STD -	Sexually Transmitted Diseases
TRA -	Theory of Reasoned Action
UKZN -	University of KwaZulu-Natal
VMMC -	Voluntary Medical Male Circumcision
VOICE -	Vaginal and Oral Interventions to Control the Epidemic
WHO -	World Health Organization

TABLE OF CONTENTS

DECLARATION.....	ii
ACKNOWLEDGMENTS.....	iii
ACROYNMS AND ABBREVIATIONS	iv
TABLE OF CONTENTS	v
FIGURES	viii
TABLES	ix
LIST OF APPENDICES.....	xi
ABSTRACT	xii
Chapter 1: Introduction.....	1
1. 1. Background.....	1
1. 1. 1. What is the problem?.....	1
1. 1. 2. Research question.....	1
1. 1. 3. What is known so far	1
1. 1. 4. What needs to be known?	3
1. 1. 5. Why is the problem important?	3
1. 1. 6. How will the study solve the problem?.....	4
1. 2. Statement of the research problem.....	4
1. 3. Aim of the research.....	4
1. 4. Specific objectives of the research.....	5
Primary Objective	5
Secondary Objective.....	5
1. 5. Summary.....	5
Chapter 2: Literature Review.....	6
2. 1. HIV infection and prevention efforts in South Africa.....	6
2. 2. HIV prevention clinical trials	8
2. 3. Youth as a target population for HIV prevention research.....	11
2. 4. Willingness to participate in HIV prevention research	13
2. 5. Race and social identity in South Africa	14
2. 6. The theory of reasoned action	17
2. 7. The theory of reasoned action and HIV prevention.....	18
2. 8. Summary.....	22

Chapter 3: Research Methodology	24
3.1. Introduction	24
3.2. Type of research	24
3.3. Study design	24
3.4. Research population	24
3.4. 1. Selection of research population group	24
3.4. 2. Type of sample	25
3.4. 3. Size of sample	25
3.5. Data sources	26
3.5. 1. Measurement instrument	26
3.5. 2. Variables	27
3.5. 3. Reliability of measurement instrument	30
3.5. 4. Measures to ensure validity	30
3.5. 5. Pilot study	33
3.5. 6. Data collection	33
3.5. 7. Data handling	34
3.6. Statistical analysis	34
3.6. 1. Descriptive statistics	34
3.6. 2. Analysis of variance (ANOVA)	34
3.6. 3. Multiple linear regression	35
3.6. 4. Confirmatory factor analysis	35
3.7. Ethics	35
3.7. 1. From research ethics committee (REC)	35
3.7. 2. Permission from concerned authorities	35
3.8. Summary	36
Chapter 4: Results	37
4. 1. Introduction	37
4. 2. Presentation of data	37
4.2.1. Survey racial demographics	37
4.2.2. Participant demographics	39
4.2.3. Willingness to participate by gender and race	44
4.2.4. Descriptive statistics for factors and items of the CRIS	46
4.2.5. Analysis of variance (ANOVA) for factor scores	60

4.2.6. Multiple linear regression of demographic variables	66
4.2.7. Confirmatory Factor Analysis (CFA)	72
4.2.8. Summary	75
Chapter 5: Discussion	78
5. 1. Introduction	78
5. 2. Analysis of data.....	78
5. 3. Limitations.....	89
5. 3. 1. Selection bias	89
5. 3. 2. Confounding	89
Chapter 6: Conclusions and Recommendations	90
6. 1. Introduction	90
6. 2. Conclusion	90
6. 3. Recommendations	91
References	92
Appendices.....	97
Appendix 1: Measurement Instrument	97
Appendix 2: Online informed consent	102
.....	103
Appendix 3: Biomedical Research Ethics Committee (BREC) approval	104
Appendix 4: UKZN Registrar Approval.....	105
Appendix 5: Scientific approval from UKZN Postgraduate Education Committee.....	106

FIGURES

Figure 1: The theory of reasoned action..... 18

Figure 2: The construct path diagram of the Clinical Research Involvement
Scale (CRIS) 22

Figure 3: Consort diagram displaying the selection process for inclusion of data
for analysis 25

TABLES

Table 1:	Comparison of university racial demographic versus survey racial demographics.....	35
Table 2:	Participant demographics by race group.....	37
Table 3.1:	Willingness to participate in HIV prevention research by race group and gender.....	43
Table 3.2:	ANOVA results of willingness to participate by race.....	44
Table 3.3:	Independent samples T-test of willingness to participate by gender.....	44
Table 4.1:	Descriptive statistics by race group per factor.....	45
Table 4.2:	Descriptive statistics by race group per scale item for behavioural beliefs.....	48
Table 4.3:	Descriptive statistics by race group per scale item for outcome evaluation.....	50
Table 4.4:	Descriptive statistics by race group per scale item for normative beliefs.....	51
Table 4.5:	Descriptive statistics by race group per scale item for motivation to comply.....	52
Table 4.6:	Descriptive statistics by race group per scale item for attitudes.....	53
Table 4.7:	Descriptive statistics by race group per scale item for subjective norms.....	55
Table 4.8:	Descriptive statistics by race group per scale item for organizational involvement.....	56
Table 4.9:	Descriptive statistics by race group per scale item for personal relevance.....	57
Table 5.1:	One-way ANOVA on factor scores.....	59
Table 5.2a:	Bonferroni test for multiple comparisons for behavioural beliefs score.....	59
Table 5.2b:	Bonferroni test for multiple comparisons for outcome evaluation score.....	60
Table 5.2c:	Bonferroni test for multiple comparisons for normative	

	beliefs score.....	61
Table 5.2d:	Bonferroni test for multiple comparisons for attitudes score.....	61
Table 5.2e:	Bonferroni test for multiple comparisons for subjective norms score.....	62
Table 5.2f:	Bonferroni test for multiple comparisons for organizational involvement score.....	63
Table 5.2g:	Bonferroni test for multiple comparisons for personal relevance score.....	63
Table 6a:	Multiple linear regression of behaviour intention (total score on scale) and demographic variables (Initial model selection).....	65
Table 6b:	Multiple linear regression – Final model selection.....	66
Table 6c:	ANOVA of the multiple linear regression (Final model).....	68
Table 6d:	Model summary for final regression model.....	68
Table 7a:	Confirmatory factor analysis of the clinical research involvement scale – Unstandardized regression weights: (Default model).....	69
Table 7b:	Standardized regression weights: (Default model).....	70
Table 7c:	Squared multiple correlations.....	70
Table 7d:	Chi square result (Default model).....	71

LIST OF APPENDICES

Appendix 1:	Measurement instrument.....	94
Appendix 2:	Online informed consent.....	99
Appendix 3:	Biomedical Research Ethics Committee (BREC) approval.....	101
Appendix 4:	UKZN Registrar approval.....	103
Appendix 5:	Scientific approval from UKZN Postgraduate Education Committee.....	104

ABSTRACT

Introduction

Willingness to participate in clinical trials is a crucial element in recruitment of suitable participants for intervention trials. Measurement of willingness to participate assists in determining community preparedness for clinical trials, such as HIV vaccine trials. Therefore, researchers have developed a Clinical Research Involvement Scale (CRIS) to assess willingness to participate modelled on the Theory of Reasoned Action. The CRIS was tested in the USA and was noted that it would benefit from additional testing in other populations.

Aim

The purpose of this study is to determine whether racial differences exist in willingness to participate and explore potential factors associated with willingness to participate in HIV prevention research.

Methods

A cross sectional analytic study was conducted. The CRIS was administered to university students aged 18-45 at the University of KwaZulu-Natal in South Africa. The CRIS was administered online with a demographic questionnaire to facilitate evaluation of possible associations between willingness to participate and age, gender, relationship status, parity, religion, education status, student status, employment status and access to private health care. Participation was once-off at the time of completing the scale.

Results

The study enrolled 636 participants, two thirds being female. An effective sample size of 509 was considered for analysis after data was cleaned for accuracy and completeness. The results indicated that all students across all race groups were willing to participate in HIV prevention research. However, when considering factors that affected willingness to participate, statistically significant differences were noted. Based on the differences amongst these factors, Black students expressed greater intention to participate compared to White and Indian students. The CRIS was deemed a reliable instrument in this

population; however in its current structure it did not show strong validity. Validity improved if the factors of motivation to comply and outcome evaluations were removed in this population.

Discussion

The study findings are specific to students of the University of KwaZulu-Natal and cannot be generalized to other populations. The racial differences in factors that affect willingness to participate indicate differences in risk perception and seeking access to better quality healthcare.

Recommendations

The CRIS should be used in other student populations to assess its validity.

(350 words)

Chapter 1: Introduction

1. 1. Background

1. 1. 1. What is the problem?

The problem explored in this study is the possible differential willingness to participate in HIV prevention clinical trials between different race groups in South Africa.

1. 1. 2. Research question

- 1) Are there racial differences in willingness to participate in HIV prevention clinical research in university students at the University of KwaZulu Natal?
- 2) Are there racial differences in factors affecting willingness to participate in HIV prevention clinical research in university students at the University of KwaZulu Natal?

1. 1. 3. What is known so far

Clinical trials are currently underway and active in recruitment both locally and internationally to test candidate products aimed to prevent HIV infection. These candidate products include HIV vaccines, anti-retrovirals (ARVs) as prevention, ARV-based microbicides and the ARV-containing (dapavirine) vaginal ring (1, 2).

In order to prove the effectiveness of such products it is essential that clinical trials to test these products enrol and retain a sufficient and representative proportion of the at-risk population. The importance of diversity in clinical trials is well established. Clinical trials are a means of evaluating medical interventions and if certain population groups are under-represented this affects generalizability of the findings to the population as a whole and prevents subgroup analysis to determine if ethnic origin influences the intervention (3). UNAIDS has released guidelines entitled *“Ethical considerations in the conduct of biomedical HIV prevention trials”*, which addresses, amongst other aspects,

community participation in HIV prevention research. It states that in order *“to ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials”*(4). UNAIDS further released supplemental guidelines in respect of community participation in the form of *Good Participatory Practice*, which details how communities and community stakeholders should be engaged in HIV prevention research in order to build good relationships amongst the affected community (4).

Willingness to participate in clinical trials has been researched in the US amongst African-Americans, Hispanics and Non-Hispanic Whites. (5). Research suggests that African-Americans were less willing to participate in clinical trials given the racially directed transgressions of past clinical studies (5). However, racial differences in willingness to participate in clinical trials has not been widely studied in South Africa (6). A pertinent study on *Racial Differences in Public Perception of Voluntariness of Medical Research Participants in South Africa* by Barsdorf and Wassenaar (2005) revealed similar findings to US-based studies, (6). However, 17 years into democracy it would be beneficial to determine whether this dynamic has changed, especially in young adults who have been raised in a democratic South Africa and are eligible to participate in future HIV prevention trials.

A group of researchers from Emory University and the University of Georgia developed The Clinical Research Involvement Scale (CRIS) that utilizes the constructs of a behavioural theory, namely the Theory of Reasoned Action (TRA) to assess willingness to participate in clinical trials. The scale has been tested in the realm of HIV

biomedical prevention research. The TRA has been applied and holds relevance to HIV prevention research such as HIV vaccine acceptability and condom usage (7). The CRIS is reported as a reliable and valid tool to measure multiple determinants of study participation (8). However, this instrument was only tested in the USA and will benefit from further testing in different populations (8). Hence, this study aims to utilize this instrument in South Africa.

1. 1. 4. *What needs to be known?*

Do university students of different racial groups that exist in South Africa express a differential willingness to participate in HIV prevention research?

Do factors affecting willingness to participate in HIV prevention clinical research differ amongst university students of different racial groups in South Africa?

1. 1. 5. *Why is the problem important?*

It is important that study populations are representative of population diversity especially when testing a candidate public health product that could possibly be used widely. Hence, it is important to explore the willingness of different race groups to participate in clinical trials to test candidate products, in order to streamline and improve recruitment strategies.

Worldwide, young people between 15-24 years comprise approximately half of all new HIV infections and over 6000 people in this age range contract HIV daily (9). In South Africa, HIV prevalence amongst this age group was as high as 8.9% in 2013 (10) which further highlights the risk of HIV amongst young people. This forms the basis for the rationale for focusing on university students. Literature suggests that university students in countries with high HIV prevalence, such as South Africa, are a potential target for HIV prevention research since university students engage in high risk

behaviour such as inconsistent use of condoms, abuse of narcotics and alcohol, especially during sexual encounters and having multiple sex partners (9, 11).

Although a large proportion of university students who are at risk of contracting HIV will never become infected, disease prevention in this population should still remain a public health priority (11). University students are the next generation of leadership and the impact of HIV on students will have both health and economic ramifications (9).

1. 1. 6. How will the study solve the problem?

This study may help researchers conducting HIV prevention clinical trials understand how particular dynamics and variables of research participation differ amongst race groups in South Africa and may thus potentially inform guidance and strategies on recruitment of these race groups into clinical trials.

1. 2. Statement of the research problem

To determine whether there are racial differences in willingness to participate and factors affecting willingness to participate in HIV prevention clinical research in university students at the University of KwaZulu Natal.

1. 3. Aim of the research

The aim of this study is to determine possible racial differences in willingness to participate amongst university students in KwaZulu Natal, South Africa, in HIV prevention trials using the Clinical Research Involvement Scale (CRIS).

1. 4. Specific objectives of the research

Primary Objective

The primary objective of this study is to use the constructs of the Theory of Reasoned Action to explore racial differences in factors that affect willingness to participate in HIV prevention research.

Secondary Objective

The secondary objective of this study is to determine the validity of the CRIS for use in University students in KwaZulu-Natal, South Africa.

1. 5. Summary

In light of South Africa's hyper-endemic, generalized epidemic of HIV, all race groups are at risk of HIV infection, with youth being particularly affected. As a result, research into novel HIV prevention strategies is vital. Youth and young adults should be willing to participate in such research. Therefore measurement of willingness to participate in HIV prevention research is essential in order to determine community preparedness.

Chapter 2: Literature Review

2. 1. *HIV infection and prevention efforts in South Africa*

South Africa's HIV epidemic is defined by the Joint United Nations Programme on HIV/AIDS (UNAIDS) as a hyper-endemic epidemic, because more than 15% of its population aged 15- 49 is infected with HIV (12). HIV prevalence amongst South African youth aged 15-24 years of age is amongst the highest in the world at 8.5% in 2013 (10), thus highlighting the urgent need to identify effective HIV prevention approaches (13).

HIV prevention approaches that have been explored can be divided into the following groups, (1) Behavioural, (2) Structural, (3) Biomedical (14).

Behavioural interventions are grouped into the widely used A, B, C principles, i.e. **A**bstain, **B**e Faithful and **C**ondomise (15). This message has been communicated widely across the South African media.

The use of condoms, both male and female, is a proven method to prevent HIV. However, this intervention is highly user dependent and no control exists over condom use, which is particularly important in relationships or societies where power relations between males and females are not equal (16). Social and cultural beliefs might restrict the use of male condoms such that some cultures might view condom use as not being "macho" (17). Barriers to the use of male condoms include discomfort, reduced sensitivity, disruption to intercourse and some have experienced condom failure (18).

The female condom, a physical barrier against acquisition of STIs and conception, was designed as a female initiated method to prevent infection but partner co-operation still plays a part in its successful use (19). Common challenges to its use include difficulty with insertion, and have been reported so in up to 50% of women who participated in

studies to test this method (20). Other concerns include its appearance, its negative effect on sexual pleasure and that it is noisy (21).

Although such interventions do have an effect on curbing the spread of HIV in spite of its challenges, their effectiveness is solely user dependent and therefore cannot be used in isolation but rather should form part of a package of prevention. It is recommended that these strategies should be used in conjunction with structural approaches and biomedical interventions, thereby creating a comprehensive prevention package (14).

Structural approaches include social, economic, and political interventions that can improve health outcomes by increasing the willingness and ability of individuals to practice prevention (22). Structural approaches reduce an individual's HIV-related vulnerability by creating the conditions in which people can adopt safer behaviours (22). For example, the IMAGE study conducted in South Africa aimed to reduce gender-based HIV vulnerabilities such as sexual violence, women's economic dependency on men and women's lack of in-depth information on HIV and modes of transmission (22). The study offered women microfinance in order to be able to pursue microenterprises, thereby aiming to reduce women's HIV vulnerability by strengthening their economic options (22). The study also included HIV education and mobilisation of local action against gender-based violence (22). The results of the IMAGE study showed that over a 2-year period, intimate partner violence reduced by 55% in the intervention group compared to the control group (22). Evidence also indicated that the intervention also improved social capital, empowerment and household well-being (22). However, none of these factors appeared to have a direct effect on reduction of HIV incidence. In the 1990's, Uganda put together a national level response to the HIV epidemic including multipronged structural approaches (22). This proved effective in reducing HIV incidence. However, effectiveness could not be attributed to one specific

intervention (22). At present there is limited evidence on the effectiveness of structural approaches due to the complexity of their measurement (22).

Biomedical interventions include voluntary medical male circumcision (VMMC), vaccines, oral pre-exposure prophylaxis (Oral PrEP) and microbicides to name a few (23). VMMC is a surgical intervention to reduce the risk of HIV infection (24). It has been shown to provide a significant degree of protection against acquisition of HIV infection (24). However, barriers to its acceptance as an HIV prevention method are cost, fear of pain, concerns about safety and issues regarding culture and religion (25). Interventions such as HIV vaccines, oral PrEP and microbicides are currently under clinical study worldwide to determine safety and effectiveness. These are reviewed briefly below.

2.2. HIV prevention clinical trials

HIV prevention strategies offer the best chance to combat the HIV pandemic (26). Currently candidate products that are being tested in clinical studies include HIV vaccines, anti-retrovirals (ARVs) as prevention, ARV-based microbicides and the ARV-containing (dapavirine) vaginal ring (1, 2)

There have been numerous phase I and II HIV vaccine clinical trials over the past years testing candidate vaccines, yielding disappointing results (27). One such study conducted in 2007 in South Africa was the HVTN 503 (Phambili) study (28). This study was a multi-site phase 2b test of concept HIV vaccine trial that tested the safety and efficacy of the subtype B MRK Ad5 HIV vaccine in populations with predominant subtype C infection (28). The HVTN 503 study began enrolling a heterosexual cohort of males and females, aged 18 to 35, in Jan 2007 and was prematurely stopped in September 2007 as a result of Data Safety Monitoring Board (DSMB) findings from the interim analysis of the

HVTN 502/ STEP study that indicated that the STEP study met the criteria of futility (28). The STEP study had started enrolling participants in 2004 and was testing the same MRK Ad5 HIV vaccine in a cohort of primarily men who have sex with men (MSM) in North America, Australia, South America and the Caribbean. Further analysis of STEP study data indicated that certain subgroups of male participants who received the vaccine showed an increased acquisition of HIV-1 infection (28). This subgroup was identified as men who had pre-existing immunity to the Ad5 vector and/or who were uncircumcised (28). However, the RV144 vaccine trial, a phase IIb clinical trial in Thailand, was the first vaccine study to show modest efficacy of 31% (29).

ARVs used for pre-exposure prophylaxis gained much recognition through their success in prevention of HIV from mother to child transmission (23). Thus, the concept of potentially administering ARVs for HIV prevention in uninfected people stems from this success. There have been numerous clinical trials in different populations testing the ARVs, tenofovir and truvada (combination of tenofovir and emtricitabine). One such study is the VOICE (Vaginal and Oral Interventions to Control the Epidemic), study, which was conducted from 2010 over a two-year period in Durban, South Africa (1). The VOICE study tests ARVs for prevention in two different formulations, namely tenofovir and truvada tablets and a microbicide in the form of 1% tenofovir gel (1).

A microbicide is a product that is applied to the vagina or rectum with the intention of reducing the acquisition of sexually transmitted diseases (STIs), including HIV (30). ARV based microbicides are the second generation of microbicides (31). Unlike first generation microbicides (which were non-specific compounds), they specifically target HIV and the cells it infects since its active formulation contains ARVs specific against HIV replication (31). Clinical trials of candidate first-line microbicides conducted in South Africa, such as COL-1492 (Nonoxyol-9) and Carraguard have been unsuccessful (32) , with COL-1492 causing

toxic effects that would increase susceptibility to HIV infection (33). Clinical trials that have already been conducted in South Africa to test candidate ARV-based microbicides include the CAPRISA 004 1% tenofovir gel study (1) and the trials to test these products further include the MTN-003 (VOICE) study and the FACTS 001 study (1). Unfortunately, on the 16th of September 2011, the NIAID Prevention Trials DSMB recommended that VOICE stop the tenofovir tablet arm since it did not show a difference in effect between the tenofovir tablet and its matching placebo (futility) (1). Subsequently, on the 17th of November 2011, the DSMB recommended that the 1% Tenofovir gel arm of the VOICE study should be stopped due to futility (1). No safety concerns were identified with use of either the tenofovir tablets or 1% tenofovir gel (1). Prior to the natural end of the VOICE study, the USA Food and Drug Administration (FDA) approved Truvada as an effective agent for pre-exposure prophylaxis (PrEP) based on evidence from numerous studies (34).

Another potential HIV prevention intervention being tested under clinical study is the ARV-medicated vaginal ring. Vaginal rings have been used since the early nineties for steroidal contraception and oestrogen replacement therapy (35). It is a drug delivery system that provides sustained / controlled release of the active product contained within it (35). The non-nucleoside reverse transcriptase inhibitor (NNRTI), dapivirine has been tested for use in silicone elastomer vaginal rings and is the only microbicide to be evaluated clinically in a vaginal ring (35). This vaginal ring delivers dapivirine to the cervical / vaginal mucosa and vaginal fluid at concentrations greater than that indicated to inhibit HIV-1 in studies done in vitro (36). Phase I and II studies have shown that the dapivirine vaginal ring is both safe and well tolerated (35).

The target population for such trials include: heterosexual women or homosexual men between 18 and 45 years of age.

It is important to note that due to the lack of an effective cure for HIV, the field of HIV prevention research is a dynamic one with both successes and failures, as is evident from the aforementioned literature. However, the goalpost always remains the same which is ultimately to combat the HIV pandemic.

2. 3. Youth as a target population for HIV prevention research

The rationale for focusing on university students stems from literature that suggests that university students in high HIV prevalence countries could be a possible target population for HIV prevention research (37). In a generalized HIV epidemic like South Africa where heterosexual sex is the predominant mode of transmission of HIV infection, young people, especially women, are at risk (38). HIV-related prevention trials usually involve the traditionally high-risk individuals such as sex workers and drug users. (11). However, there is a growing body of evidence to suggest that the number of university students becoming infected with HIV is increasing (11). Clinical trials such as the SAVVY vaginal gel (C31G) trial conducted in Nigeria reported that approximately 35% of its participants were students (39). In the CAPRISA 004 trial urban site, 19.4% of the participants had some tertiary education and 38.1% had completed high school (40) thus eligible to enter post-secondary education institutes.

University students also engage in high-risk sexual behaviour such as inconsistent condom use, abuse of drugs and alcohol during sexual encounters and having multiple sexual partners (9, 11). Worldwide, young people between the aged 15-24 years comprise approximately half of all new HIV infections and over 6000 people within this age range contract HIV daily (9). In South Africa, heterosexual exposure is the chief mode of transmission of HIV and approximately half of the new infections are amongst people aged 15-24 years (9). Literature has shown that in spite of increased income or educational attainment, the risk of HIV is not

eliminated amongst South Africans; therefore South African university students do possess a risk for contracting HIV (9). Amongst Black South Africans, literature has suggested an increase in HIV prevalence with increasing levels of education (9).

A study by the Higher Education HIV/AIDS Program (HEAIDS) on HIV and AIDS in the Higher Education Sector, released its findings of the study on HIV seroprevalence and related factors at the University of KwaZulu Natal in 2008 (41). The findings suggest that the overall prevalence of HIV amongst students at UKZN is 2.4%. The study suggests that aggregating the data hides a worrying dynamic and stratification by age group reflects the true situation (41). The findings illustrated an HIV prevalence of 1.1% amongst 18-24 year olds and 15.1% amongst 25-34 year olds thereby illustrating the level of risk students are exposed to (41). In terms of risk profiles, a total of 24.1% of students reported having more than one sexual partner in the preceding 12 months (41). To this end HEAIDS led a collaborative initiative called the *First things First HIV Campaign* which was launched in 2012 with the aim to reach 23 higher education institutions (42). The *First things First HIV Campaign* is a HIV counselling and testing (HCT) campaign aimed at strengthening existing institutional HIV programmes and to contribute to the 2012-2016 National Strategic Plan for HIV, STIs and TB by maximizing opportunities for HIV testing (42). The campaign included all members of the university community with particular focus on first year students since first year students are exposed to a new environment and therefore exposed to new risk factors (42).

Although a large proportion of university students who are at risk of contracting HIV will never become infected, disease prevention in this population should still remain a public health priority (11). University students are the next generation of leadership and the impact of HIV on students will have both health level and economic ramifications (9).

2. 4. *Willingness to participate in HIV prevention research*

Public participation plays a pivotal role in the development of medical advances; however, the recruitment of individuals to participate in medical research remains a challenge to biomedical researchers (43). Much is known about willingness to participate in medical research from the perspective of patients and those at-risk of getting a particular disease. However, very little is known about the attitudes and willingness of the general public to participate in medical research (43). The general public is of particular importance since it is from this population that the potential pool of participants for future prevention studies are derived (43).

Barriers to participation in HIV prevention research such as vaccine trials include concerns about personal safety, fear, mistrust, misunderstanding about study design, social risk and pragmatic obstacles (44). A report from the WHO-UNAIDS consultation on HIV vaccine trials suggests that willingness to participate in trials varies with age, educational level and perceived risk (45).

A study conducted in India that looked at willingness to participate in HIV vaccine trials found that many married women despite contracting HIV from their spouses still did not consider themselves as a group that was potentially at risk of HIV infection (45). The findings of this research suggest that the main reason for refusal to participate was low perceived risk in this population (45). In terms of low perceived risk, in South Africa, HIV is unfortunately seen by some as a 'black disease', in part due to media portrayal of AIDS being young, Black and female (46), thereby leading to the possibility that other race groups could perceive themselves at lower risk.

Race is a complex issue and may be a proxy for a range of social and cultural factors which include knowledge, information and beliefs about HIV and AIDS related stigma and discrimination (47). Racial differences

in willingness to participate has been widely researched on US based race groups such as African-Americans, Hispanics and Non-Hispanic Whites (5). It has been found that African-Americans were less willing to participate in clinical trials given the transgressions of past clinical trials, such as the Tuskegee Syphilis study (5). The Tuskegee Syphilis study was a classic example of discriminatory and unethical medical research, where African American men enrolled in a study were reportedly deliberately denied access to syphilis treatment in order to study the natural history of syphilis infection (48). However, racial differences in willingness to participate in clinical trials have not been widely studied in South Africa (6). A pertinent study on *Racial Differences in Public Perception of Voluntariness of Medical Research Participants in South Africa* (2005) by Barsdorf and Wassenaar revealed similar findings to US based studies, stating that black participants scored low in terms of perceived voluntariness to medical research compared to Whites and Indians. This could be due to negative perceptions of medical research derived from the Apartheid regimen as a result of health service inequality based on racial identity (6).

2. 5. Race and social identity in South Africa

Social identity in South Africa has been created by the institution of racial categories during the Apartheid regime (49). Social identity refers to “*the ways in which individuals and collectivities are distinguished in their social relations with other individuals and collectivities*” (50). Government legislation under the form of the Populations Regulations Act of 1950 classified the population as Coloured*, Black, White or Indian/Asian (51). Coupled with this social classification was a distinct hierarchical order in which Blacks were at the bottom of this social hierarchy, Whites at the top and Coloureds and Indians/Asians in the middle (52). Geographical segregation accompanied the racial stratification under the Group Areas Act of 1950 (51), thereby keeping different racial categories clustered in distinct locations. In 1994 the Apartheid regime was dissolved and South

Africa began its new identity as a democratic country, dissolving legislature that used race as a source of discrimination (49). However, despite post-apartheid changes to bring about equality and equal opportunity amongst these categories, the socially constructed institutionalized categories of race are still operational and are reproduced in South Africa (49). In post-apartheid South Africa, individuals still see themselves as belonging to apartheid defined racial categories (49). This is due in part to South Africa's racial history but also due to post-apartheid nation building which reinforces the population's collective identity as a "rainbow nation"(49). Therefore race remains pertinent in social and cultural terms, with the majority of South Africans using racial categorization in everyday life (49). In the apartheid regime racial categorization took on a vertical structure and was used as tool for segregation and economic divide, but in post-apartheid times, racial categorization takes on a horizontal structure encompassing social identity (49). A study by Dolby (2000) (53) looked at racial identity amongst students at a Durban High School. Dolby's findings suggest that the school was highly racially segmented but not in a vertical manner with a hierarchical structure but rather in a horizontal non-hierarchical manner defined by social influences that dictate social behaviour. A study by Tredoux and Finchilescu (2010) (54) looked at relations between racial and ethnic groups at 4 South African universities. The findings of this study indicate that even though there were excellent opportunities for students to form friendships across races and ethnicities, intergroup friendship was low (54). This further highlights the role of racial categorization in modern social structure.

In addition, as a result of this historical segregation, trust relationships amongst these socially constructed groups might be affected (49). Burns (2004) conducted an experiment on racial trust relationships using a trust game amongst 337 high school students in 6 different high schools in Cape Town. The students ranged from 14 to 19 years of age belonging to either the Black, White or Coloured race grouping and were

considered to belong to the 'new South Africa', having grown up in post-apartheid South Africa. The trust game comprises of a proposer and a partner who are physically separated in respect of location. The proposer is given a fixed amount of money by the researcher and must decide how much will be shared with the partner. Whatever the proposer shares with the partner will be tripled by the researcher. In turn the partner must decide how much of the tripled amount will be shared with the proposer. The proposer was given a picture of the partner and the partner a picture of the proposer in order for the pair to determine racial identity. The results indicate a pattern of distrust towards Black partners even by Black proposers. White proposers were less likely to engage in an exchange with a Black proposer. Coloured and Black students did engage in exchanges but at a lower level when compared with non-Black students. Therefore the results of this study showed differential trust relationships by racial category. Ashraf *et al* (2003) (55) conducted a similar study amongst 129 university students in Cape Town with similar findings. These results suggest an influence of racial identity on decision making.

Trust levels may differ based on differing beliefs (49). As observed from these studies, differences can be exacerbated in segmented societies, such as that which exists in South Africa, where group affiliation can be based on some individual attribute such as race, ethnicity or gender (49). If an individual values the identity of the group, that individual is likely to respond to normative behaviour defined by affiliation with the group, making the norms of this group particularly relevant (49). Therefore, it can be postulated that such group affiliation, be it by race, ethnicity or gender, has an influence on normative beliefs (49). Normative beliefs influence subjective norms, and subjective norms can be seen as a function of behaviour intention, as defined by the Theory of Reasoned Action (56), which will be explained in more detail below.

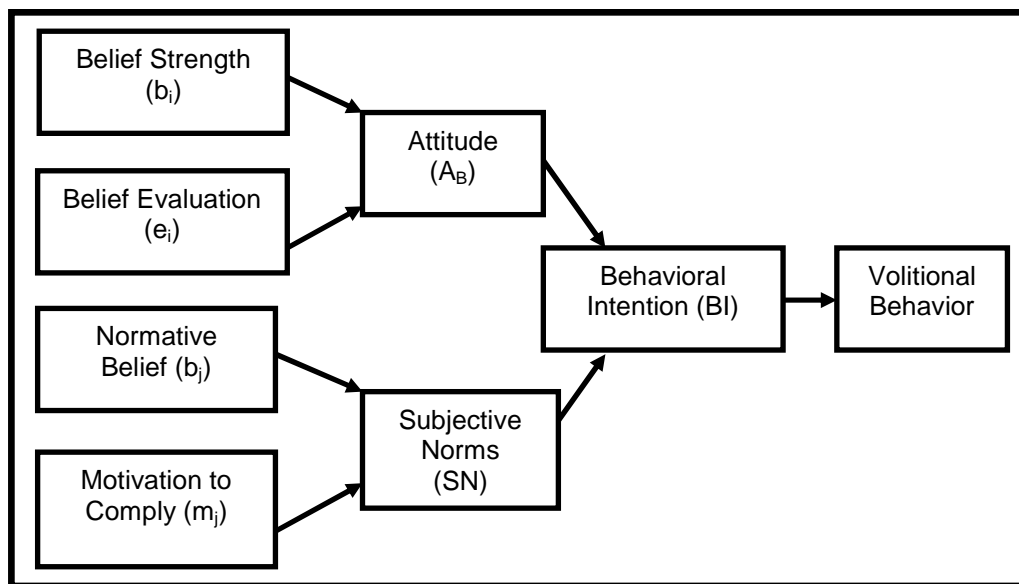
* Please note that the term "Coloured" used in this paper refers to an official race group classification in South Africa denoting an individual of mixed race.

2. 6. *The theory of reasoned action*

The Theory of Reasoned Action (TRA) is a behavioural theory that has been formulated by Fishbein and Azjen (1975) (56) to explain volitional behaviour as depicted in Figure 1. Volitional behaviour is defined as the act of making a conscious choice or decision. The theory states that the strongest predictor of voluntary behaviour is one's behavioural intention to perform a particular behaviour.

The theory further states that behavioural intention is influenced by both attitudes and subjective norms towards the particular behaviour (57). An attitude as defined by the TRA is an affective response towards performing a particular behaviour (57). A subjective norm is one's belief about what significant members of one's social / family network feel about him/her performing a particular behaviour (57). The TRA suggests that an attitude toward performing a particular behaviour is a function of the beliefs held towards performing this behaviour (57). Therefore, attitudes towards a particular behaviour are influenced by belief strength and belief evaluation (57). Belief strength is defined as the certainty with which the belief is held and belief evaluation is the extent to which the attribute is judged to be negative or positive (57).

The TRA suggests that subjective norms are a function of normative beliefs and motivation to comply with a normative belief (57). A normative belief is defined as the perceived expectation of significant others regarding the voluntary behaviour (57). Motivation to comply is defined as the real or imagined pressure that one feels for one's behaviour to match the perceived expectation of others (57).



$$BI = (A_B)W_1 + (SN)W_2$$

Where, $(A_B) = \sum b_i e_i$, and $(SN) = \sum b_j m_j$,

Figure 1: The theory of reasoned action (56)

The TRA has been tested in a variety of research areas which included dieting (58), condom use (59), limiting sun exposure (60), consumption of GMO foods (61) and determinants of HIV and AIDS prevention behaviour (62), to name a few. The overall findings of the available evidence, confirm the validity of the TRA through the observed relationship of behaviour intention on the performance of volitional behaviour (57).

2. 7. *The theory of reasoned action and HIV prevention*

The TRA has had a widespread influence on public health (63) and has been applied to a range of healthcare behaviours displaying its utility (62). It has greatly influenced the field of HIV prevention (63) and has been shown to be a relevant and useful conceptual approach for understanding and promoting of HIV/AIDS-prevention behaviour (62). It has been used to explain safe sex behaviour and condom usage in different populations (7) and has guided the development of effective HIV risk reduction behavioural interventions through behavioural prediction models (63).

A study by Fisher *et al* (1995) (62) used the theory of reasoned action to help guide prospective investigations of the psychological determinants

of HIV / AIDS preventive behaviour amongst three distinct at-risk populations. The populations identified for this study include gay men, heterosexual university students and heterosexual high school students (62). The results of this study strongly confirmed the theory of reasoned action with regression analysis illustrating that intention to engage in nearly every HIV / AIDS preventive behaviour under study was a function of both attitudes towards that action and subjective norms (62). Both attitudes and subjective norms accounted for a large proportion of variance in behaviour intentions across all studied behaviour and across populations under study (62).

A study by Bosompra (2001) (64) used the TRA to assist in understanding the beliefs that underlie Ghanaian university students' attitudes, subjective norms and intentions about the consistent use of condoms. The findings of this study suggest that students who believed that advantages of using condoms was greater than the disadvantages were more likely to have intentions of using condoms (64). In addition students, who believed that significant individuals think that people who are sexually active should use condoms, are more likely to intend to use condoms (64). These findings support the findings of previous studies conducted and confirmed that both subjective norms and attitudes are determinants of behaviour intention (64). This opposes the argument that behavioural theories are "Western Models" and do not apply to other cultures (56). The findings indicate that since subjective norms are a significant predictor of intention to use condoms, HIV education program interventions should not only focus on the individual but also on sexual partners and the broader social network in order to enhance peer acceptance.

Project Respect, a randomized control trial conducted by Kamb *et al.*, (1998) (65) at STD clinics in five USA cities amongst males and females aged 14 years and older, recruited 5758 participants. These participants were randomly assigned to receive one of 3 models of HIV post-test

counselling namely enhanced counselling, brief counselling and didactic messages (65). The enhanced counselling comprises 4 sessions across 3 to 4 weeks and is based on the theory of reasoned action and social cognitive theory. This intervention aimed to change elements underlying condom use. The first session lasts 20 minutes and the subsequent sessions last 60 minutes each. HIV test results are given at session 3. Each session is built upon the lessons learned from the preceding session. During the first 3 sessions, behavioural goals are set in which the participant arrives at a small behavioural risk-reduction step that could be achieved before the next session. At the 4th session a longer term risk reduction plan is put in place. The brief counselling intervention comprises 2 sessions across 7 to 10 days and was modelled on CDC's recommended HIV counselling for patients attending public clinics and HIV test sites. The main objective of this brief counselling intervention was to assess actual versus self-perceived HIV/STD risk. The first session lasts 20 minutes and was identical to the enhanced counselling intervention in which a behavioural goal was set. This exercise is performed in order to assist the participant in identifying any barriers to risk reduction, to develop an acceptable and achievable risk reduction plan and to support patient-initiated behaviour change. The second session also lasts 20 minutes during which the HIV test results are discussed, additional counselling, review of barriers and facilitators to achieving the behavioural goal and a longer term risk reduction plan is also discussed. The didactic messages intervention comprises 2 sessions across 7 to 10 days. This intervention was performed to mimic what is being done in most STD clinics. The participant is not engaged in interactive counselling but rather two brief messages about HIV and STD prevention are delivered. Session one lasts 5 minutes and is conducted by the clinician who examines the patient. Session 2 also lasts 5 minutes where participants are informed of their HIV test result, limitations of the test and provided with didactic prevention messages about HIV and STDs. The participant is then asked if they have questions.

As explained above, the experimental risk reduction interventions of enhanced and brief counselling were derived from elements of the TRA (65). Counsellors aimed to challenge risk-promoting beliefs, attitudes and behaviour intentions and challenged false beliefs about HIV transmission and negative attitudes towards condom use (65). The results of this form of interactive client-centred counselling achieved an overall reduction in STD incidence of approximately 30% at 6 months of follow up and 20% at 12 months of follow up (65). Therefore, this TRA based intervention was effective in reducing the incidence of STD's and therefore by inference, reduced HIV infections.

In terms of behavioural prediction models, the constructs of TRA can also be used to predict clinical trial involvement (8). Using the constructs of the TRA, a Clinical Research Involvement Scale (CRIS) was developed by Frew *et al* (2010) (8) in an attempt to understand factors driving participation in HIV vaccine trials as depicted in Figure 2.

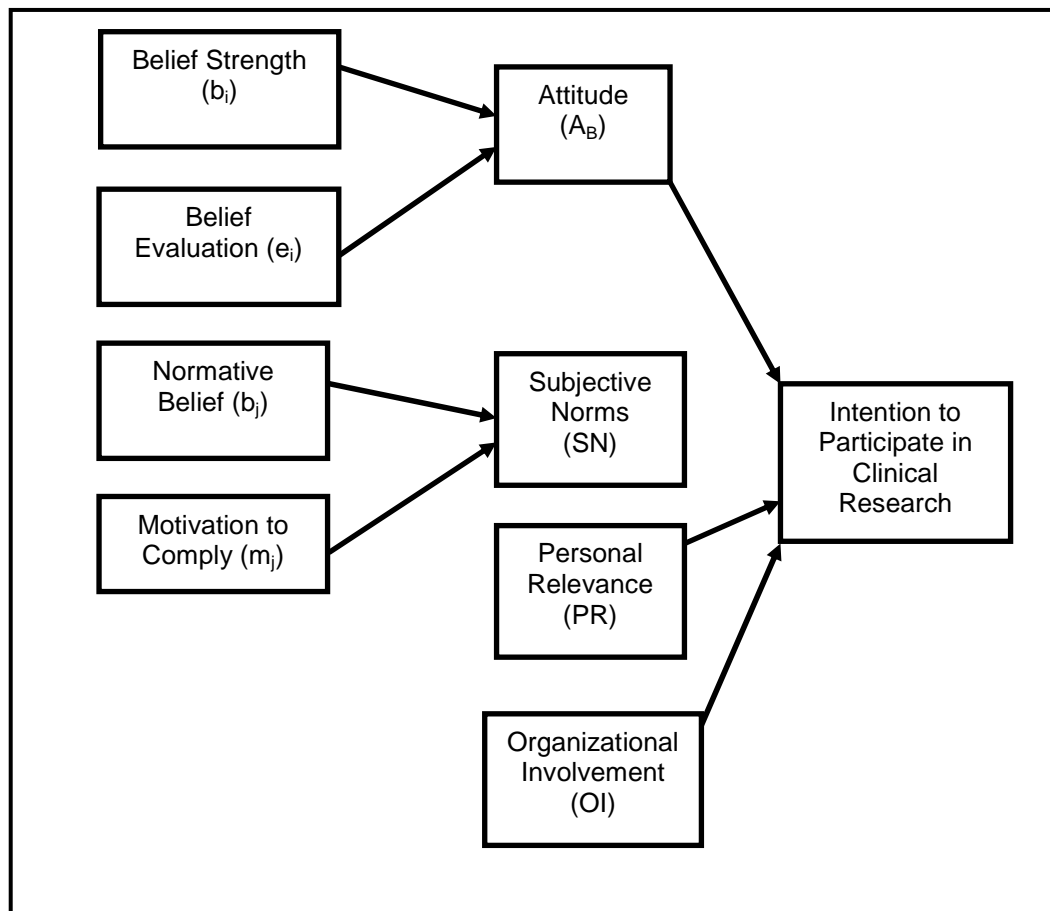


Figure 2: The construct path diagram of the Clinical Research Involvement Scale (CRIS) (8)

This scale aims to measure social and network level factors that may influence study recruitment (8). The CRIS was found to be a valid and reliable instrument for measuring multiple determinants of participation in clinical research (8). The CRIS thus can effectively measure the likelihood that individuals will participate in clinical research (8). The elements of the CRIS and its use in this study are explained in more detail below.

2. 8. Summary

The literature reviewed illustrates the plethora of research that is being undertaken in order to produce an effective comprehensive package of HIV prevention approaches. The literature suggests that use of the theory of reasoned action can assist in determining the communities'

intentions to use these candidate products, thereby informing as to the future potential utility and uptake of these products as effective HIV prevention agents.

Chapter 3: Research Methodology

3.1. *Introduction*

The purpose of this research was to determine racial differences in willingness to participate amongst university students in KwaZulu-Natal, South Africa, in HIV prevention trials using a Clinical Research Involvement Scale (CRIS), which will be described fully in this chapter.

3.2. *Type of research*

The type of research used in this study is epidemiological research.

3.3. *Study design*

An observational, analytic, cross-sectional study design was used.

3.4. *Research population*

3.4. 1. Selection of research population group

The study was conducted amongst university students at the five campuses (Howard College, Medical School, Westville, Edgewood and Pietermaritzburg) of the University of KwaZulu-Natal. Students who are between the ages of 18 and 45 and who are South African citizens were included in the study. Foreign students were excluded from the study sample since as it is assumed that they could have different perceptions of HIV prevention due to socialization in different social structures and epidemiological settings from South Africa.

3.4. 2. Type of sample

Non-probability sampling was used in the form of a voluntary sample of individuals who were willing to participate in the survey. This may introduce some bias as it samples only those willing to volunteer.

3.4. 3. Size of sample

After 64 postings on the UKZN Notice System, a sample size of 636 students was reached comprising of 507 Blacks, 52 Whites, 55 Indians, 8 Coloureds, and 14 Other (Non-South African students). For purposes of data analysis the 'Other' group was excluded. Participants who did not answer more than 3 questions in the survey were also excluded. Therefore the effective sample size for analysis was 509 participants as displayed in figure 3.

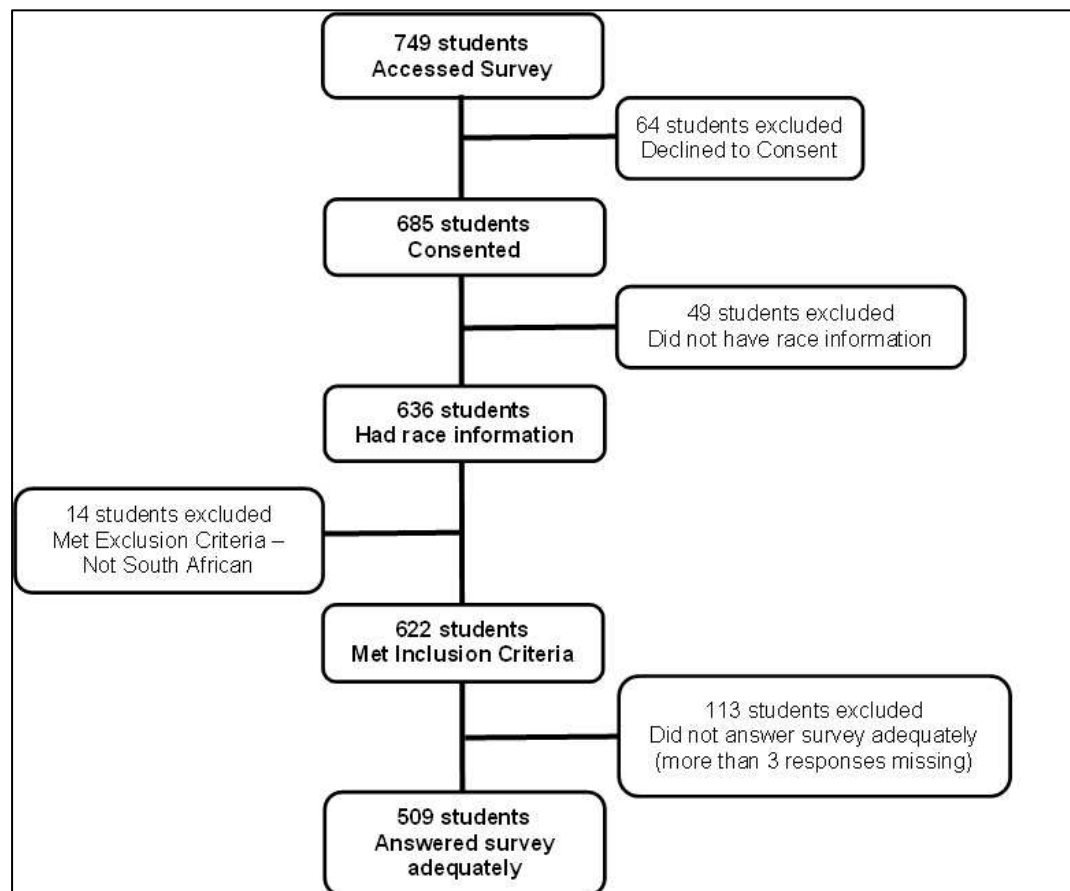


Figure 3: Consort diagram displaying the selection process for inclusion of data for analysis

3.5. *Data sources*

3.5. 1. Measurement instrument

The measurement instrument that was used in the study was a structured questionnaire / scale distributed on-line (See Appendix 1).

The questionnaire consisted of two sections. The first section consisted of demographic information. The second section of the questionnaire was a 5-point Likert scale (range from strongly agree to strongly disagree) consisting of 40 items. The scale measured the following:

- **Attitudes:** factors like negative attitudes toward health research, its role in the community and benefits arising from clinical study participation.
- **Subjective norms:** questions about whether family and friends would support their participation in HIV prevention research. Favourable social opinion of research involvement is theorized to increase participatory intention
- **Behavioural beliefs:** beliefs about medical research favouring participatory behaviour should increase intentions to become a study volunteer.
- **Outcome evaluations:** issues related to HIV vaccine trial participation such as concerns related to time and trouble related to study participation, fear of needles, risk aversion, etc.
- **Normative beliefs:** participant beliefs about the effects of research on a community should influence subjective norms and participatory intentions
- **Motivation to comply:** the theorized influence of family, friends and others on behavioural performance will exert

social pressure to act or engage in avoidance of performing behaviour (i.e. rejecting the opportunity to become a study volunteer). Greater self-agency should lead to greater participatory intention.

- **Organizational involvement:** measures perception of the clinical research site and the extent to which persons identify with its research agenda.
- **Personal relevance of volunteerism:** may exert influence of behavioural intention

3.5. 2. Variables

Demographic Variables:

- Age (defined as age at last birthday)
- Gender
- Race group (categorized as either White, Black, Indian, Coloured or Other as per Statistics SA defined categories)
- Religion type
- Frequency of practice of religion
- Relationship status
- Pregnancies
- Children
- Student status
- Employment
- Education (highest level completed)
- Medical care system

As depicted in Figure 1, the formula for the TRA expresses mathematically is as follows:

$$\text{Behaviour Intentions (BI)} = (A_B)W_1 + (SN)W_2$$

Where, $(A_B) = \sum b_i e_i$, and $(SN) = \sum b_i m_j$,

In this equation the variable to measure the construct of *attitude* (A_B) in the TRA, is also a function of behavioural beliefs (b_i) and outcome evaluation (e_i):

- Attitudes (A_B) assesses:
 - altruism in respect of participation in HIV prevention research
 - HIV as a community concern
 - HIV testing as a benefit of study participation
 - medical care as a benefit of study participation
- Behavioural beliefs (b_i) assesses:
 - community benefit
 - positive impact of actions on others
 - positive attitude towards participation in HIV prevention study
 - benefit from research
 - impact of involvement in HIV prevention research
 - non-monetary motivation to participate
- Outcome evaluation (e_i) assesses:
 - negative attitude towards participation in HIV prevention research
 - time constraints
 - perceive risk of participation
 - fear of needles

In this equation, the variable to measure the construct of *subjection norms* (SN) in the TRA, is also a function of normative beliefs (b_j) and motivation to comply (m_j):

- Subjective norms (SN) assesses:
 - opinion of referent others on HIV prevention research

- approval of study participation by referent others
- support of study participation by referent others
- Normative beliefs (b_j) assesses:
 - referent doctor's approval of participant's involvement in the study
 - approval of study participation by work colleagues
 - support of study participation by immediate family
 - opinion of referent others on participant's involvement in HIV prevention research
 - support of referent others
 - impact of religious leader on study participation
- Motivation to comply (m_j) assesses:
 - concern over peers' perceptions
 - actions towards family perceptions
 - actions towards friends' perceptions
 - submission to superiors
 - peer/social pressure

The factor of *Organizational involvement*, which although not included in the original TRA (Figure 1) does have an effect on behaviour intentions as depicted in Figure 2:

- Organizational involvement assesses:
 - expression of self through the research organization
 - perception of involvement of others with the research organization
 - perception of others in respect of your involvement with the research organization

The factor of *Personal relevance*, which although not included in the original TRA (Figure 1) does have an effect on behaviour intentions as depicted in Figure 2:

- Personal Relevance assesses:
 - empowerment through being involved with the research organization
 - feeling a sense of community in the cause
 - feeling a sense of belonging through participation
 - altruistic intentions
 - sense of liberation through involvement in the case
 - sense of purpose in the cause

3.5. 3. Reliability of measurement instrument

The CRIS was tested by Frew *et al* (2010) (8), for reliability amongst similar samples and over different time periods. The results of the testing indicate that each of the 8 scales exhibit strong reliability with a standardized Cronbach's alpha statistic that range from 0.734 to 0.918 (8). Frew *et al* (2010) (8) however did encourage further reliability testing in different populations, other than lower-income Southern populations in the USA. Cronbach's alpha statistic was calculated for this study and exhibited a standardized Cronbach's alpha statistic of 0.890. Literature suggests that a minimum of 0.70 (66) and a maximum Cronbach's alpha of 0.90 is recommended, since any value higher denotes redundancy of certain items (67).

3.5. 4. Measures to ensure validity

The CRIS was tested by Frew *et al* (2010) (8) for factor structure validity. Results from their factor analysis support the validity of the constructs and produced factor loadings

in the range of ≥ 0.448 to ≤ 0.867 . The confirmatory factor analysis demonstrated an acceptable model fit to the data (RMSEA = 0.068, CFI = 0.835).

As a secondary objective of this study, confirmatory factor analysis was performed to determine whether results are comparable with the results obtained by Frew *et al* (2010) (8) and the data suggests a mediocre model fit to the data (RMSEA = 0.113; CFI=0.919).

3.5. 4. 1. Internal validity - Reduction of bias

In order to reduce bias in the study the following measures were undertaken:

Selection bias

Under-coverage bias

Under-coverage bias occurs when certain members of the population are not represented sufficiently within the study. This occurs frequently during non-probability sampling. In order to reduce this form of bias; the request for participation in the study was placed in a central location that all members of the student community could access.

Non-response / Refusal Bias

Non-response bias occurs when surveys are sent to a random sample of the population and some refuse to participate. Non-response was taken into account when calculating the desired sample size in order to buffer against this form of bias.

The non-response / refusal rate found in this study was 8.5%. Therefore, the majority of students who

accessed the survey participated hence the effect of this form of bias was low.

Information bias

Response bias

Response bias in questionnaire studies may occur due to leading and ambiguous questions. In order to reduce this form of bias, scale items within the CRIS was tested in 3 phases by Frew *et al* (2010) (8), namely the formative phase, the pilot phase and the instrument validation phase. The formative phase assessed item phrasing and respondent understanding (8). The researchers tested the questionnaire amongst participants of the 'African American Outreach Initiative' (8). It was found that the question achieved acceptable values for the Flesch Reading Ease and Flesch-Kincaid Scores, corresponding to a 6 to 8th grade reading level fluency (8).

Social desirability bias

Social desirability bias occurs when participants respond to questions in a manner that is deemed socially acceptable rather than answering honestly. In order to reduce this form of bias the questionnaire is anonymous and self-administered hence; participants are not linked to their responses. Thus participant privacy and confidentiality is assumed to reduce social desirability bias.

3.5. 4. 2. Threats to external validity

The study may lack external validity as the study sample is restricted to campuses of one University in

KwaZulu-Natal and findings might not be generalizable to other universities or youth in the general population in South Africa.

3.5. 5. Pilot study

No formal pilot study was undertaken; however a pilot period was informally instituted during the first month of data collection. Responses and response rates were assessed and no issues were raised.

3.5. 6. Data collection

Data was collected from students at the University of KwaZulu-Natal (UKZN) from 25 September 2012 to 30 November 2012 and from 18 February to 05 April 2013. The break in data collection between 30 November and 18 February was as a result of the scheduled University vacation, at which point students would not be available. A notice to volunteer to participate in this research by completion of a questionnaire was placed on the University's online notice system on a daily basis and could be viewed by all registered students belonging to the University community. As part of the UKZN notice system procedures, all notices are emailed to students on a daily basis, with links to the online notice system. Repeat postings of the notice were done on a daily basis except during university vacation periods. The students who volunteered to participate completed an online informed consent (See Appendix 2) before proceeding to complete the online questionnaire. All data collection was thus done online.

3.5. 7. Data handling

The data from the online questionnaire was automatically recorded on the online survey system which is password protected. The data was then exported from the survey system to Excel, SPSS and SPSS AMOS. The exported data was checked for validity before any analyses were performed. The data was checked for validity in the form of face validation and checking for inconsistencies and gaps.

3.6. *Statistical analysis*

All data was analyzed using the IBM SPSS Statistics 21 program for Windows (68) or the SPSS AMOS Graphics program (69).

3.6. 1. Descriptive statistics

Descriptive statistics for demographic variables was determined using Microsoft Excel. Means as a measure of central tendency were determined for numeric variables such as age. Categorical data was described in the form of whole numbers and percentages.

Descriptive statistics for each construct were determined using the IBM SPSS Statistics 21 program for Windows. Means as a measure of central tendency and associated standard deviations were determined for both summed constructs and individual items in each construct.

3.6. 2. Analysis of variance (ANOVA)

The ANOVA was performed using IBM SPSS Statistics 21 Program for Windows.(68) The Bonferroni test was selected as test for multiple comparisons. Statistical significance level was set at $p < 0.05$, as per accepted statistical standards for determining significance.

3.6. 3. Multiple linear regression

A multiple linear regression analysis was performed using IBM SPSS Statistics 21 Program for Windows (68). The initial model was selected based on uncategorized independent demographic variables at a significance level of $p < 0.10$ for forward selection. Based on the significance criterion, independent variables were selected and categorized into dichotomous variables for the final model. Selection of independent variables in the final model were based on the significance level of $p < 0.05$ (backward elimination).

3.6. 4. Confirmatory factor analysis

A confirmatory factor analysis was performed on the SPSS AMOS graphics program (69). The model was created based on the design that all observed variables (constructs) are loaded onto a single factor (behaviour intention). Significance was set at $p < 0.05$ for each observed variable. Goodness of fit was determined by measurement of comparative fit index (CFI) and root mean square error approximation (RMSEA).

3.7. Ethics

3.7. 1. From research ethics committee (REC)

Full approval of this study was granted from the UKZN Biomedical Research Ethics Committee (BREC) on 14 August 2012 (See Appendix 3). Application for recertification was made in August 2013.

3.7. 2. Permission from concerned authorities

Permission from the UKZN Registrar for placing the request to participate on the UKZN online Notice System was granted on 10 May 2012 (See Appendix 4).

Scientific approval to conduct this study was obtained from the UKZN Postgraduate Education Committee (School of

Nursing and Public Health) on 14 September 2012 (See Appendix 5).

3.8. *Summary*

A cross-sectional, analytic study was conducted in order to determine if there are racial differences in willingness to participate as well as if there are racial differences in factors affecting willingness to participate. The data collection instrument included two sections. The first section consisted of demographic variables and the second section consisted of the clinical research involvement scale (CRIS) which was used to measure willingness to participate and intention to participate in HIV prevention research. The study population consisted of registered University of KwaZulu-Natal students between 18 and 45 years who were South African citizens. Descriptive statistics in the form of percentages and means were calculated for demographic variables and factors within the CRIS. An ANOVA was conducted to determine if there are racial differences in factors affecting willingness to participate in HIV prevention research. A multiple linear regression was conducted to determine the effect of demographic variables on intentions to participate. A confirmatory factor analysis was conducted in order to determine validity of the CRIS in this population.

Chapter 4: Results

4. 1. *Introduction*

The online survey data collection between September 2012 and March 2013 yielded 636 respondents. However, after study exclusion criteria and data exclusion criteria were taken into account, the effective sample size for analysis was 509 participants. The main factor of interest in the analysis was self-reported race grouping and descriptive and analytic statistics presented reflect this. Race groups included in the analysis were the South Africa census defined race groups of Black, White, Indian and Coloured (10).

4. 2. *Presentation of data*

4.2.1. Survey racial demographics

This sub-section illustrates the survey racial demographics compared to the university racial demographics from which this sample was derived.

Table 1: Comparison of University racial demographics versus survey racial demographics

Race	2011	2012	2013	Average	% at University	% in Survey	% Difference	Representation of Source Population
African	26283	27038	26726	26682	64.08	80.38	16.30	Over Representation
Coloured	930	945	873	916	2.20	1.20	-1.00	Similar Representation
Indian	11488	10899	10273	10887	26.14	8.43	-17.71	Under Representation
Other	141	132	125	133	0.32	2.24	1.92	Over Representation
White	3395	3143	2532	3023	7.26	7.75	0.49	Similar Representation
TOTAL	42237	42157	40529	41641	100.00	100	0.00	

In Table 1, the average percentage per race group at the University based on the average of estimates for year 2011, 2012 and 2013 was compared to the percentage race distribution in this survey. It was found that for both White and Coloured race groups, the race distribution in the survey was proportionate to that found in the University community. African students were over-represented in the survey by approximately 16.3% and Indian students were under-represented in the survey by approximately 17.7%. Population estimates in South Africa suggest that country comprises of approximately 79.8% Africans, 9% Coloured, 2.5% Indian and 8.7% White (10). Hence, the racial demographics of the university were not representative of the general South African population in that Indians were overrepresented and Blacks, Whites and Coloureds were under-represented in the study from a national perspective.

4.2.2. Participant demographics

This sub-section illustrates responses to demographic variables that were assessed in this survey. The data are presented by race category.

Table 2: Participant demographics by race group

Participant Demographics (N= 622)	Black (n = 507)		White (n = 52)		Indian (n = 55)		Coloured (n = 8)		Totals n = 622	
Age (Mean - years)	23		23		23		23			
Age Category (n, %)	N	%	N	%	n	%	n	%	N	%
Under 18*	4	0.79	0	0	0	0	0	0	4	0.6
18-29	454	89.55	46	88.46	51	92.73	6	75	557	89.5
30-39	19	3.75	6	11.54	1	1.82	1	12.5	27	4.3
40-49*	10	1.97	0	0	3	5.45	0	0	13	2.1
Older than 49*	0	0	0	0	0	0	1	12.5	1	0.2
Missing Data	20	3.94	0	0	0	0	0	0	20	3.2
Gender (n, %)	N	%	N	%	n	%	n	%	N	%
Male	176	34.71	16	30.77	12	21.82	2	25	206	33.1
Female	327	64.5	36	69.23	43	78.18	6	75	412	66.2
Missing Data	4	0.79	0	0	0	0	0	0	4	0.6
Religion (n, %)	N	%	N	%	n	%	n	%	N	%
Agnostic	5	0.99	10	19.23	2	3.64	0	0	17	2.7
Atheist	6	1.18	9	17.31	1	1.82	0	0	16	2.6
Christian (Catholic)	130	25.64	7	13.46	1	1.82	2	25	140	22.5
Christian (Protestant)	311	61.34	21	40.38	3	5.45	4	50	339	54.5
Hindu	0	0	0	0	34	61.82	1	12.5	35	5.6
Muslim	6	1.18	0	0	13	23.64	0	0	19	3.1
Other [#]	36	7.1	5	9.62	0	0	0	0	41	6.6
Missing Data	13	2.56	0	0	1	1.82	1	12.5	15	2.4

Religion – Frequency of Practice (n, %)	N	%	N	%	n	%	n	%	N	%
Weekly	338	66.67	12	23.08	26	47.27	4	50	380	61.1
Monthly	57	11.24	3	5.77	4	7.27	0	0	64	10.3
During Festive Season	32	6.31	7	13.46	13	23.64	1	12.5	53	8.5
Not Practicing	46	9.07	23	44.23	4	7.27	0	0	73	11.7
Other ^{##}	29	5.72	7	13.46	8	14.55	1	12.5	45	7.2
Missing Data	5	0.99	0	0	0	0	2	25	7	1.1
Relationship Status (n, %)	N	%	N	%	n	%	n	%	N	%
Not married (no partner)	164	32.35	12	23.08	16	29.09	2	25	194	31.2
Not married (non-live in partner)	271	53.45	19	36.54	29	52.73	5	62.5	324	52.1
Not married (live-in partner)	18	3.55	13	25	0	0	0	0	31	5.0
Not married (casual partners)	24	4.73	3	5.77	4	7.27	0	0	31	5.0
Married	23	4.54	5	9.62	6	10.91	1	12.5	35	5.6
Separated	3	0.59	0	0	0	0	0	0	3	0.5
Divorced	1	0.2	0	0	0	0	0	0	1	0.2
Missing Data	3	0.59	0	0	0	0	0	0	3	0.5
Pregnancies (n, %)	N	%	N	%	n	%	n	%	N	%
0	243	47.93	31	59.62	37	67.27	4	50	315	50.6
1	64	12.62	2	3.85	2	3.64	1	12.5	69	11.1
2	16	3.16	1	1.92	3	5.45	1	12.5	21	3.4
3	4	0.79	2	3.85	0	0	0	0	6	1.0
4+	0	0	0	0	0	0	0	0	0	0.0
Missing Data	4	0.79	0	0	1	1.82	0	0	5	0.8
Children (n, %)	N	%	N	%	n	%	n	%	N	%
0	401	79.09	47	90.38	50	90.91	6	75	504	81.0
1	84	16.57	3	5.77	2	3.64	1	12.5	90	14.5
2	14	2.76	1	1.92	3	5.45	1	12.5	19	3.1
3	2	0.39	0	0	0	0	0	0	2	0.3
4+	1	0.2	0	0	0	0	0	0	1	0.2

¹ The variable of frequency of practice for religion was asked in alignment with religion to determine whether the respondents are actively practicing their religion, since religion is noted as a determinant of sexual behaviour

Missing Data	5	0.99	1	1.92	0	0	0	0	6	1.0
Student Status (n, %)	N	%	N	%	n	%	n	%	N	%
Full-Time	493	97.24	44	84.62	48	87.27	6	75	591	95.0
Part-Time	9	1.78	8	15.38	7	12.73	2	25	26	4.2
Missing Date	5	0.99	0	0	0	0	0	0	5	0.8
Employment Status (n, %)	N	%	N	%	n	%	n	%	N	%
Full-Time	22	4.34	9	17.31	5	9.09	1	12.5	37	5.9
Part-Time	71	14	18	34.62	13	23.64	0	0	102	16.4
Not Employed	407	80.28	25	48.08	37	67.27	6	75	475	76.4
Missing Data	7	1.38	0	0	0	0	1	12.5	8	1.3
Education (Highest Level Completed) (n, %)	N	%	N	%	n	%	n	%	N	%
Matric	87	17.16	3	5.77	8	14.55	1	12.5	99	15.9
Diploma / Certificate	6	1.18	0	0	3	5.45	0	0	9	1.4
Degree (1 st Year)	49	9.66	8	15.38	2	3.64	1	12.5	60	9.6
Degree (2 nd Year)	94	18.54	7	13.46	9	16.36	1	12.5	111	17.8
Degree (3 rd Year)	132	26.04	6	11.54	15	27.27	3	37.5	156	25.1
Degree (4 th Year)	38	7.5	3	5.77	3	5.45	2	25	46	7.4
Postgraduate (Honours)	69	13.61	13	25	12	21.82	0	0	94	15.1
Postgraduate (Masters)	30	5.92	11	21.15	2	3.64	0	0	43	6.9
Postgraduate (PHD)	0	0	1	1.92	1	1.82	0	0	2	0.3
Missing Data	2	0.39	0	0	0	0	0	0	2	0.3
Medical Care² (n, %)	N	%	N	%	n	%	n	%	N	%
Public Sector	327	64.5	5	9.62	7	12.73	4	50	343	55.1
Private Sector	170	33.53	46	88.46	46	83.64	4	50	266	42.8
Other ^{###}	8	1.58	1	1.92	2	3.64	0	0	11	1.8
Missing Data	2	0.39	0	0	0	0	0	0	2	0.3

* Age inclusion criteria for this study is 18 to 45 years of age, therefore all participants who fell out of this range were not included in the analysis

Responses include: African religion, Ja Man, Jehovah's Witness, Nazareth Baptist Church (Shembe), Pantheist, Traditional, Zionist

Responses include: Daily, During University Vacations, Every Second Day, Hardly, When I Get Time, Varies, Never, Once A Year, Quarterly, Twice A Week

Responses include: Private and Public, None, Cash, Traditional Healers

² The variable of medical care assessed where respondents accessed medical care from since access to medical care might be a contributing factor to participation in HIV prevention research

Table 2 represents the demographic variables categorized by race grouping. It must be noted that even though Coloured students are represented proportionately to the university racial demographics, they have not been mentioned in the analysis because the sample size for this group is too small (less than 10 respondents).

The mean age across all race groups was 23 years of age, thereby allowing a uniform comparison across all race groups based on age. Across all race groups females represented approximately two thirds of the survey population.

Christian (Protestant) was identified as the most common religion amongst Blacks, Whites and Coloureds at 61.34%, 40.38% and 50% respectively. Hinduism was the most common religion amongst Indian students with 61.82%. Regarding religion, 66.67% of Black students, 47.27% of Indian students and 50% of Coloured students practiced their religion on a weekly basis. However, 44.23% of White students were non-practicing.

In respect of relationship status, the majority of Black (53.45%), White (36.54%), Indian (52.73%) and Coloured (62.50%) students reported not being married but having partner that they do not live with. However, 25% of White students reported having a live in partner (not married) compared to 3.55% of Black students and 0% of Indian and Coloured students. Similar proportions of all students across all race groups reported no partner at 32.54% for Black students, 23.08 for White students, 29.09 for Indian students and 25% for Coloured students. Across all race groups, the majority (over 50%) of female students reported no pregnancies.

For students who reported one pregnancy, the proportion of Black students (12.62%) was four times that of White (3.85%) and Indian (3.64%) students. The proportion of Coloured students who reported one pregnancy was 12.5%, however, the due to the small sample size ($n = 8$) of this race group, these results were not considered in the analysis. Regarding pregnancies, the

majority of all female students across all race groups reported no children. For students who reported one child, the proportion of Black students was 16.57%, compared to 5.77% of White students and 3.64% of Indian students.

The majority of students across all race groups were full time students who were not employed. In terms of part time employment, a greater proportion of White students (34.62%) and Indian students (23.64%) reported part-time employment compared to Black students (14%). Amongst all race groups there was no clear majority in respect of level of education with a similar distribution of responses per race group, as was expected since the survey was open to all South African students in the University community. The lack of a clear majority denotes a distribution of responses across all levels of education.

The majority of Black students (64.50%) reported utilization of the public health sector in comparison to 9.62% of White students and 12.73% of Indian students. The majority of White students (88.46%) and Indian students (83.64%) reported making use of the private sector for health care, thereby displaying a marked difference in utilization of health services across race groups.

4.2.3. Willingness to participate by gender and race

This sub-section illustrates responses to the item; *I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS*, which is used to determine willingness to participate. The data are stratified by gender and race.

Table 3.1: Willingness to participate in HIV prevention research by race group and gender

Behavioural Belief																		
I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS																		
RESPONSE	Female								Male								Totals	
	Race Group								Race Group									
	Black		White		Indian		Coloured		Black		White		Indian		Coloured			
	n = 269	(%)	n = 33	%	n = 36	%	n = 5	%	n = 139	%	n = 14	%	n = 9	%	n = 0	%	n = 505	%
Strongly Agree	141	52.4	15	45.5	19	52.8	2	40.0	90	64.7	7	50.0	4	44.4	0	0	278	55.0
Agree	81	30.1	11	33.3	14	38.9	3	60.0	38	27.3	6	42.9	3	33.3	0	0	156	30.9
Total Agreed	222	82.5	26	78.8	33	91.7	5	100.0	128	92.1	13	92.9	7	77.8	0	0.0	434	85.9
Neither Agree / Disagree	31	11.5	5	15.2	0	0.0	0	0.0	9	6.5	1	7.1	1	11.1	0	0	47	9.3
Disagree	11	4.1	2	6.1	2	5.6	0	0.0	2	1.4	0	0.0	0	0.0	0	0	17	3.4
Strongly Disagree	5	1.9	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	11.1	0	0	7	1.4
Total Disagreed	47	17.5	7	21.2	3	8.3	0	0.0	11	7.9	1	7.1	2	22.2	0	0.0	71	14.1

Table 3.2: ANOVA results of willingness to participate by race

ANOVA					
Behavioural Beliefs [I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS]					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.894	3	.298	.379	.768
Within Groups	396.859	505	.786		
Total	397.752	508			

Table 3.3: Independent samples T-test of willingness to participate by gender

	Levene's Test for Equality of Variances	
	F	Sig.
Behavioural Beliefs [I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS]	8.568	.004

Table 3.1 represents willingness to participate in HIV prevention research by gender, further stratified by race. Willingness to participate was determined by the behavioural beliefs construct item “*I would participate in a HIV prevention research study because it would help prevent HIV/AIDS*” The results indicated that the majority of students (85.9%) across all race groups irrespective of gender were willing to participate. Table 3.2 displays the ANOVA results of willingness to participate in respect of race, and yielded non-significant results ($p = 0.768$). Willingness to participate appears to be higher amongst males compared to females, which is statistically significant ($p = 0.004$) as noted by the results of the independent samples T-test in Table 3.3.

Willingness to participate amongst Indian males was lower compared to Indian females, however, the sample size for Indian males (n=9) was small and cannot be seen as a true difference.

4.2.4. Descriptive statistics for factors and items of the CRIS

This sub-section contains descriptive statistics for scores in the form of mean and standard deviation stratified by race for the 8 factors assessed in the CRIS. In this section the 8 factors are expanded into the individual items that make up the factors. Descriptive statistics for scores in the form of mean, standard deviation, minimum and maximum values are displayed.

Table 4.1: Descriptive statistics by race group per factor

Race Group		Behavioural Beliefs Score*	Outcome Evaluation Score**	Normative Beliefs Score***	Motivation to Comply Score****	Attitudes Score [#]	Subjective Norms Score ^{##}	Organization Involvement Score ^{##}	Personal Relevance Score*
Black (n = 412)	Mean	11.76	14.96	12.40	17.38	7.81	6.33	6.60	12.92
	Std. Deviation	3.749	3.151	4.006	3.900	2.550	2.323	2.527	4.928
White (n = 47)	Mean	14.79	14.64	13.34	17.02	11.64	7.19	7.68	17.09
	Std. Deviation	3.237	2.793	3.655	3.131	2.345	1.813	2.023	3.827
Indian (n = 45)	Mean	13.36	12.91	14.11	16.64	10.89	7.67	7.51	15.71
	Std. Deviation	3.827	3.502	4.603	4.012	2.715	2.276	2.474	5.841
Coloured (n = 5)	Mean	13.80	15.00	14.80	19.00	11.80	8.40	8.40	16.00
	Std. Deviation	4.087	1.000	2.168	1.581	2.280	2.302	.548	5.339
Total (N=509)	Mean	12.20	14.75	12.66	17.30	8.47	6.55	6.80	13.58
	Std. Deviation	3.826	3.186	4.049	3.832	2.890	2.318	2.499	5.109

* Positive Scores (7-14), Neutral Scores (21), Negative Scores (28-35); ** Positive Scores (16 -20), Neutral Scores (12), Negative Scores (4-8);

*** Positive Scores (6-12), Neutral Scores (18), Negative Scores (24-30); **** Positive Scores (20 – 25), Neutral Scores (15), Negative Scores (5-10); # Positive Scores (5-10), Neutral Scores (15), Negative Scores (20 – 25); ## Positive Scores (3-6), Neutral Scores (9), Negative Scores (12 – 15)

Table 4.1 contains the mean summative response per factor and indicates that, in terms of *Behavioural Beliefs* which assessed community and personal benefit of health research and willingness to participate in HIV prevention research, all students had positive behavioural beliefs towards HIV prevention research and displayed willingness to participate. However, the intensity varied with Black students displaying more positive behavioural beliefs than (mean total score = 11.76) White (mean total score = 14.79) and Indian (mean total score = 13.36) students.

The mean summative response for *Outcome Evaluation* which assessed barriers to participation in HIV prevention research, such as perceived benefit, time, risk and dislike of needles indicated that all students display neutral responses. The intensity of responses were similar across all race groups with Indians (mean total score = 12.91) displaying primarily neutral responses and White (mean total score = 14.64) and Black (mean total score = 14.96) students displaying neutral responses leaning towards positive responses, denoting that these respondents do not perceive the determinants assessed (i.e. perceived benefit, time, risk and dislike of needles) as barriers to participation in HIV prevention research.

The mean summative response for *Normative Beliefs* which assessed the approval and support of referent others towards involvement and participation in HIV prevention research indicates that all students displayed positive responses. Black students (mean total score = 12.40) display stronger positive normative beliefs (i.e. belief that referent others would be in support of their involvement in HIV prevention research) compared with White and Indian students. White (mean total score = 13.34) and Indian (mean total score = 14.11) students displayed positive responses leaning towards neutral responses to whether referent others would approve and support their involvement in this cause.

The mean summative response for *Motivation to Comply* which assessed the influence of peer perceptions and conforming to family expectations indicates that all students displayed responses between neutral and positive (i.e. being influenced by peers and family expectations). The mean total responses for Black (17.38), White (17.02) and Indian (16.64) students were closer in the scale towards neutral responses.

The mean summative response for *Attitudes*, which assessed attitudes towards HIV prevention research, the possible benefits of participation and HIV as a concern in the respective communities, indicated that all students have positive attitudes towards HIV prevention research, but the intensity varied with Black students displaying more positive attitudes (mean total score = 7.81), than White (mean total score = 11.64) and Indian (mean total score = 10.89) students.

The mean summative response for *Subjective Norms*, which assessed support of referent others towards the participant's involvement in HIV prevention research, indicated that all students displayed positive subjective norms. However, the intensity varied in that Black students (mean total score = 6.33) displayed more positive subjective norms compared to White (mean total score = 7.19) and Indian (mean total score = 7.67) students who displayed positive responses leaning towards neutral responses.

The mean summative response for *Organizational Involvement*, which assessed positive perceptions towards clinical research organizations and expression of self through the organization, indicated that all students displayed positive perceptions towards being involved in a clinical research organization. However, the intensity varied in that Black students (mean total score = 6.60) displayed more positive responses compared to White (mean total score = 7.68) and Indian (Mean Total Score = 7.51) students who displayed positive responses leaning toward neutral responses.

The mean summative response for *Personal Relevance*, which assessed participants' sense of purpose, belonging and empowerment by being involved in

HIV prevention research, indicated that Black students (mean total score = 12.92) displayed positive responses, compared with White (mean total score = 17.09) and Indian (mean total score = 15.71) students who displayed responses leaning towards neutral.

Table 4.2: Descriptive statistics by race group per scale item for behavioural beliefs

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Behavioural Beliefs</u>																	
(1) My community would really benefit from a HIV prevention research study	1.41	0.715	1	5	2.06	0.704	1	4	1.78	0.795	1	4	2	1	1	3	1.81
(2) My actions can inspire others to act	1.63	0.765	1	5	2.32	0.958	1	5	1.84	0.796	1	4	2.6	1.14	1	4	2.09
(3) My participation in a HIV prevention study would be very good	1.5	0.699	1	4	2.17	0.732	1	4	1.82	0.834	1	5	1.8	0.837	1	3	1.82
(4) I benefit from health science research	1.77	0.885	1	5	1.49	0.585	1	3	1.84	0.861	1	4	2	1	1	3	1.77
(5) My involvement in this cause will result in more ethical research	1.83	0.882	1	5	2.32	0.935	1	4	2.14	0.824	1	4	1.6	0.548	1	2	1.97
(6) My involvement in this cause will improve my community's trust in medical research	2.01	0.943	1	5	2.68	0.887	1	5	2.29	0.944	1	4	2.2	0.837	1	3	2.29

(7) I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS	1.63	0.877	1	5	1.74	0.846	1	4	1.73	1.031	1	5	1.6	0.548	1	2	1.67
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Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree

Table 4.2 contains mean responses per Scale Item for Behavioural Beliefs and indicates that all race groups displayed positive beliefs towards HIV prevention research. Black students (mean response rounded to 1) appear to “*strongly agree*” that a HIV prevention research study would benefit their community, with White and Indians (mean response rounded to 2) on average selecting the “*agree*” response. A similar pattern was seen in the responses to “*My actions can inspire others to act and my participation in a HIV prevention study would be very good*”. Black, White and Indian students “*agree*” that they would benefit from health science research and that their involvement in this cause would result in more ethical research. Black and Indian students “*agree*” that their involvement in this cause will improve their community’s trust in medical research, with White students displaying a more neutral response. Black, White and Indian students “*agree*” that they would participate in HIV prevention research because it would help to prevent HIV/AIDS.

Table 4.3: Descriptive statistics by race group per scale item for outcome evaluation

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
Outcome Evaluation																	
(1) My participation in a HIV prevention research study would be more trouble than it's worth	4.17	0.957	1	5	4.06	0.704	2	5	3.69	0.996	1	5	4.2	0.447	4	5	4.03
(2) Even if I wanted to participate in a HIV prevention research study, I just don't have the time	3.68	1.048	1	5	3.49	0.975	1	5	3.11	1.112	1	5	3.4	0.894	2	4	3.42
(3) Participating in a HIV prevention research study seems risky	3.96	1.098	1	5	3.66	1.29	1	5	3.27	1.136	1	5	4	0.707	3	5	3.72
(4) I would participate in a HIV prevention research study, but I don't like needles	3	1.384	1	5	3.43	1.426	1	5	2.84	1.296	1	5	3.4	1.342	1	4	3.16
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree																	

Table 4.3 contains mean responses per scale item for Outcome Evaluation and indicates that Black, White and Indian students “disagree” that participation in HIV prevention research would be more trouble than it is worth. Black students “disagree” that time is a factor preventing participation in HIV prevention research with White and Indian students displaying a more neutral response. Both Black and White students “disagree” that participation in HIV prevention research seems risky with Indian students displaying

a more neutral response. Black, White and Indian students displayed a neutral response to the link between lack of participation in HIV prevention research and the fear of needles.

Table 4.4: Descriptive statistics by race group per scale item for normative beliefs

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Normative Beliefs</u>																	
(1) I think my doctor would approve of my involvement in HIV prevention research	1.95	0.947	1	5	2.13	0.992	1	5	2.16	0.878	1	4	2.4	0.548	2	3	2.16
(2) I think my work colleague would approve of my involvement in this cause	2.12	0.989	1	5	2.15	0.807	1	4	2.24	0.933	1	5	2.2	0.447	2	3	2.17
(3) My immediate family is supportive of my involvement in HIV prevention research	2.06	0.989	1	5	2.15	1	1	5	2.49	1.121	1	5	2.4	0.894	2	4	2.27
(4) Most people important to me think my involvement in HIV prevention research is good	2	0.899	1	5	2.13	0.969	1	5	2.44	1.056	1	5	2.4	0.548	2	3	2.24
(5) Most people important to me usually support my interests	1.67	0.733	1	5	1.89	0.634	1	4	1.93	0.889	1	5	2	0.707	1	3	1.87
(6) If my religious leader supported HIV prevention research, I would be inclined to get involved	2.62	1.243	1	5	2.89	0.938	1	5	2.84	1.261	1	5	3.4	1.14	2	5	2.93

Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree

Table 4.4 contains mean responses per scale item for Normative Beliefs and indicates Black, White and Indian student “agree” that their doctor, work colleagues, immediate family and important people in their live would approve of their involvement in HIV prevention research. Black, White and Indian students displayed a neutral response to the item “*If my religious leader supported HIV prevention research, I would be inclined to get involved*”.

Table 4.5: Descriptive statistics by race group per scale item for motivation to comply

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Motivation to Comply</u>																	
(1) I tend to be concerned about what people think of me, even if I don't know them	3.02	1.429	1	5	2.96	1.197	1	5	2.98	1.422	1	5	3.6	0.894	2	4	3.14
(2) I generally do what my family expects of me	2.67	1.171	1	5	2.64	0.965	1	5	2.53	1.057	1	5	3.6	0.894	3	5	2.86
(3) I would not want to do something my friends disapproved of	3.73	1.072	1	5	3.4	0.925	2	5	3.48	1.171	1	5	4	0	4	4	3.65
(4) If my superiors told me to do something I disagreed with, I would obey their wishes	3.68	1.103	1	5	3.87	0.9	2	5	3.64	1.026	1	5	4.2	0.837	3	5	3.85

(5) Sometimes I do what my friends say to do, even though I know they are wrong	4.3	0.944	1	5	4.15	0.78	2	5	4.09	1.083	2	5	3.6	1.14	2	5	4.04
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree																	

Table 4.5 contains mean responses per scale item for Motivation to Comply and indicates that Black, White and Indian students displayed a more neutral response to concerns over peer perceptions of them and conforming to family expectations. Black students tended to “disagree” with the statement “*I would not want to do something my friends disapproved of*” whereas White and Indian students displayed a more neutral response. Black, White and Indian students “disagreed” with the statement “*If my superiors told me to do something I disagreed with, I would obey their wishes*” and “*Sometimes I do what my friends say to do, even though I know they are wrong*”.

Table 4.6: Descriptive statistics by race group per scale item for attitudes

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Attitudes</u>																	
(1) I like to do good for others	1.36	0.583	1	5	1.53	0.504	1	2	1.49	0.589	1	3	2	0.707	1	3	1.60
(2) I like getting involved with HIV prevention research	1.66	0.783	1	5	2.3	0.72	1	4	2.24	0.802	1	4	2.8	0.447	2	3	2.25
(3) HIV is a serious concern in my immediate community	1.57	0.867	1	5	2.89	1.127	1	5	2.87	1.14	1	5	2.8	0.837	2	4	2.53

(4) HIV testing is a benefit of a HIV prevention study	1.37	0.616	1	4	1.87	0.741	1	4	1.76	0.773	1	4	2	0.707	1	3	1.75
(5) I would benefit from the medical care associated with a HIV prevention study	1.84	0.977	1	5	3.04	0.955	1	5	2.53	1.1	1	5	2.2	0.837	1	3	2.40
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree																	

Table 4.6 contains mean responses per scale item for Attitudes and indicates that Black and Indian students “*strongly agreed*” to altruist intentions and White students “*agree*”. Black, White and Indian students all “*agree*” that they liked the idea of getting involved with HIV prevention research. Black students “*agree*” that HIV was a serious concern in their immediate community but White and Indian students displayed a more neutral response. Black student “*strongly agree*” that HIV testing was a benefit of HIV prevention research with White and Indian students responding with “*agree*”. Black students “*agree*” that they would benefit from medical care associated with HIV prevention research but White and Indian students displayed a more neutral response.

Table 4.7: Descriptive statistics by race group per scale item for subjective norms

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Subjective Norms</u>																	
(1) Most people who are important to me think I should participate in a HIV prevention effort	2.45	0.987	1	5	3.02	0.737	1	5	3.04	0.852	1	5	2.8	0.837	2	4	2.83
(2) Most people who are important to me would approve of my involvement in this cause	2.01	0.884	1	5	2.15	0.722	1	4	2.33	0.929	1	4	2.8	0.837	2	4	2.32
(3) Most people who are important to me would support my interest in this cause	1.87	0.828	1	5	2.02	0.766	1	4	2.29	0.92	1	4	2.8	0.837	2	4	2.25
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree																	

Table 4.7 contains mean responses per scale item for Subjective Norms and indicates that Black, White and Indian students displayed a neutral response for the statement “*Most people who are important to me think I should participate in a HIV prevention effort*”. Black, White and Indian students “*agree*” that most people important to them would approve of their involvement in HIV prevention research and support their interest in HIV prevention research.

Table 4.8: Descriptive statistics by race group per scale item for organizational involvement

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
<u>Organization Involvement</u>																	
(1) Being active with a clinical research organization would help me to express who I am	2	0.955	1	5	2.91	0.952	1	5	2.44	0.967	1	5	2.6	0.548	2	3	2.49
(2) Hearing that somebody else is involved with a clinical research organization tells me a lot about that person	2.17	1.082	1	5	2.17	0.702	1	4	2.38	0.984	1	5	2.8	0.447	2	3	2.38
(3) Other would view me favourably if I volunteered for a study at a clinical research organization	2.44	1.01	1	5	2.6	0.825	1	5	2.69	0.996	1	5	3	0	3	3	2.68
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree)																	

Table 4.8 contains mean responses per scale item for Organizational Involvement and indicates that Black and Indian students “agree” that being active with a clinical research organization would help express who they are. However White students expressed a more neutral response. Black, White and Indian students all “agree” that hearing that somebody else was involved with a clinical research organization tells them a lot about that person. Black students “agree” that others would view them favourably if they volunteered for a study at a clinical research organization; however White and Indian students displayed a more neutral response.

Table 4.9: Descriptive statistics by race group per scale item for personal relevance

Factor	BLACK				WHITE				INDIAN				COLOURED				TOTAL
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean
Personal Relevance																	
(1) Being involved with a clinical research site helps me to feel empowered	1.87	0.932	1	5	2.7	0.931	1	5	2.27	1.116	1	5	2	0.707	1	3	2.21
(2) I experience a sense of community in this cause	1.8	0.848	1	5	2.7	0.931	1	5	2.33	0.977	1	5	2	0.707	1	3	2.21
(3) I feel a sense of belonging through my participation in this effort	2.04	0.981	1	5	2.91	0.88	1	5	2.6	1.009	1	5	2.4	0.894	1	3	2.49
(4) My involvement is helping to protect the rights of others	1.96	0.902	1	5	2.06	0.791	1	5	2.2	0.968	1	5	2.6	1.14	1	4	2.21
(5) I am advancing the public's health and well-being through my support of this cause	1.69	0.736	1	5	1.85	0.551	1	3	2	0.953	1	5	2.2	0.837	1	3	1.94
(6) Getting involved in a HIV prevention effort is liberating	1.89	0.865	1	5	2.64	0.919	1	5	2.33	0.977	1	5	2.4	0.894	1	3	2.32
(7) I feel a sense of purpose in this cause	1.71	0.812	1	5	2.21	0.806	1	4	1.98	1.033	1	5	2.4	0.894	1	3	2.08
Responses Key: 1 = Strongly Agree; 2 = Agree; 3 = Neither Agree or Disagree; 4 = Disagree; 5 = Strongly Disagree																	

Table 4.9 contains mean responses per scale item for Personal Relevance and indicates that Black and Indian students “agree” that being involved with a clinical research site would help them feel empowered and that they experienced a sense of community in this cause. However White students displayed a more neutral response. Black students “agree” that they would feel a sense of belonging through participation in this cause. However, White and Indian students displayed a more neutral response. Black, White and Indian students all “agree” that their involvement would be helping to protect the rights of others and that through support of this cause; they would be advancing the public’s health and well-being. Both Black and Indian students “agree” that getting involved in a HIV prevention effort was liberating. However White students had a more neutral response. Black, White and Indian students feel a sense of purpose in this cause.

4.2.5. Analysis of variance (ANOVA) for factor scores

This sub-section contains the output of the statistical test of analysis of variance for comparison of factor score means for the 8 factors of the CRIS. A Bonferroni test for multiple comparisons was also performed using race as comparison factor to determine if race was responsible for the differences in mean scores per factor.

Table 5.1: One-way ANOVA on factor scores

Summed Factor	F score	Sig.
Behavioural Beliefs	11.246	.000
Outcome Evaluation	5.790	.001
Normative Beliefs	3.447	.017
Motivation to Comply	.914	.434
Attitudes	50.042	.000
Subjective Norms	7.176	.000
Organizational Involvement	4.814	.003
Personal Relevance	13.574	.000

Significance level set at 0.05

Table 5.1 represents the one-way ANOVA F-score for each construct assessed in the scale. Since the CRIS is designed as a summative scale, the scores were summed for each construct. All items except Motivation to Comply showed statistical significance. In order to determine whether differences observed in the data were within or between race groups, a Bonferroni test for Multiple Comparisons was performed as outlined in Table 5.2.

Table 5.2a: Bonferroni test for multiple comparisons for behavioural beliefs score

Dependent Variable			Sig.
Behavioural Beliefs Score	Black	White	.000
		Indian	.040
		Coloured	1.000
	White	Black	.000
		Indian	.391
		Coloured	1.000
	Indian	Black	.040
		White	.391
		Coloured	1.000
	Coloured	Black	1.000
		White	1.000
		Indian	1.000

As illustrated in Table 5.2a, the Bonferroni test for multiple comparisons of the behavioural beliefs score indicates that there was a statistically significant difference between scores of Black students compared to White ($p < 0.001$) and Indian ($p = 0.040$) students. Whereas the comparison between White students and Indian students was not statistically significant ($p = 0.391$).

Table 5.2b: Bonferroni test for multiple comparisons for outcome evaluation score

Dependent Variable			Sig.
Outcome Evaluation Score	Black	White	1.000
		Indian	.000
		Coloured	1.000
	White	Black	1.000
		Indian	.052
		Coloured	1.000
	Indian	Black	.000
		White	.052
		Coloured	.954
	Coloured	Black	1.000
		White	1.000
		Indian	.954

As illustrated in Table 5.2b, the Bonferroni test for multiple comparisons of the outcome evaluation score illustrates that there was a statistically significant difference between scores of Black students compared with Indian students ($p < 0.001$). The comparison of scores between White and Black students ($p = 1.000$) and White and Indian students ($p = 0.052$) was not statistically significant.

Table 5.2c: Bonferroni test for multiple comparisons for normative beliefs score

Dependent Variable			Sig.
Normative Beliefs Score	Black	White	.777
		Indian	.042
		Coloured	1.000
	White	Black	.777
		Indian	1.000
		Coloured	1.000
	Indian	Black	.042
		White	1.000
		Coloured	1.000
	Coloured	Black	1.000
		White	1.000
		Indian	1.000
		Indian	1.000

As illustrated in Table 5.2c, the Bonferroni test for multiple comparisons of the normative beliefs score illustrates that there was a statistically significant difference in scores between Black and Indian students ($p = 0.042$). The comparison of scores between Black and White students ($p = 0.777$) and White and Indian students ($p = 1.000$) was not statistically significant.

Table 5.2d: Bonferroni test for multiple comparisons for attitudes score

Dependent Variable			Sig.
Attitudes Score	Black	White	.000
		Indian	.000
		Coloured	.003
	White	Black	.000
		Indian	.952
		Coloured	1.000
	Indian	Black	.000
		White	.952
		Coloured	1.000
	Coloured	Black	.003
		White	1.000
		Indian	1.000

As illustrated in Table 5.2d, the Bonferroni test for multiple comparisons of the attitudes scores illustrates that there was a statistically significant difference in scores between Black students and White ($p < 0.001$) and Indian students ($p < 0.001$). The comparison of scores between White and Indian students ($p = 0.952$) was not statistically significant.

Table 5.2e: Bonferroni test for multiple comparisons for subjective norms score

Dependent Variable			Sig.
Subjective Norms Score	Black	White	.089
		Indian	.001
		Coloured	.266
	White	Black	.089
		Indian	1.000
		Coloured	1.000
	Indian	Black	.001
		White	1.000
		Coloured	1.000
	Coloured	Black	.266
		White	1.000
		Indian	1.000

As illustrated in Table 5.2e, the Bonferroni test for multiple comparisons of subjective norms scores illustrated that there was a statistically significant difference in scores between Black and Indian students ($p = 0.001$). The comparison of scores between Black and White students ($p = 0.089$) and White and Indian students ($p = 1.000$) was not statistically significant.

Table 5.2f: Bonferroni test for multiple comparisons for organizational involvement score

Dependent Variable			Sig.
Organization Involvement Score	Black	White	.029
		Indian	.117
		Coloured	.639
	White	Black	.029
		Indian	1.000
		Coloured	1.000
	Indian	Black	.117
		White	1.000
		Coloured	1.000
	Coloured	Black	.639
		White	1.000
		Indian	1.000

As illustrated in Table 5.2f, the Bonferroni test for multiple comparisons for organizational involvement scores illustrated that there was a statistically significant difference in scores between Black and White students ($p = 0.029$). The comparison of scores between Black and Indian students ($p = 0.117$) and White and Indian students ($p = 1.000$) was not statistically significant.

Table 5.2g: Bonferroni test for multiple comparisons for personal relevance score

Dependent Variable			Sig.
Personal Relevance Score	Black	White	.000
		Indian	.002
		Coloured	.995
	White	Black	.000
		Indian	1.000
		Coloured	1.000
	Indian	Black	.002
		White	1.000
		Coloured	1.000
	Coloured	Black	.995
		White	1.000
		Indian	1.000

As illustrated in Table 5.2g, the Bonferroni test for multiple comparisons for personal relevance scores illustrated that there was a statistically significant difference in scores between Black students and White ($p < 0.001$) and Indian students ($p = 0.002$). The comparison of scores between White and Indian students ($p = 1.000$) was not statistically significant.

4.2.6. Multiple linear regression of demographic variables

This sub-section contains output data of the multiple linear regressions performed to determine the amount of variability seen in behaviour intentions (dependent variable) that can be explained by the assessed demographic variables. The forward-backward selection method was used. The initial model contained all potential independent variables (not coded into dichotomous variables) which were statistically significant. The final model contained independent variables from the initial model that were statistically significant and coded into dichotomous variables. The purpose of coding the independent variables into dichotomous variables is to allow for reference categories upon which comparisons can be made. From the variables included in the final model, only statistically significant independent variables were selected.

Table 6a: Multiple linear regression of behaviour intention (total score on scale) and demographic variables (Initial model selection)

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for	
						B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	70.328	8.097		8.685	.000	54.417	86.238
Age (at last birthday)	.379	.187	.104	2.032	.043	.013	.746
Gender	4.026	1.512	.119	2.663	.008	1.055	6.997
Race Group	4.714	1.125	.199	4.188	.000	2.502	6.925
Religion	-1.139	.673	-.076	-1.692	.091	-2.460	.183
Children	-2.877	1.579	-.091	-1.823	.069	-5.979	.224
Employment	-.188	1.391	-.006	-.135	.893	-2.922	2.546
Medical Care	4.406	1.450	.147	3.038	.003	1.556	7.255
Relationship Status	-.474	.677	-.033	-.700	.484	-1.803	.856

Table 6a illustrates the variables selected for the initial regression model. These were age, gender, race group, religion, children, employment, medical care and relationship status. The significance level for selection of independent variables in this model was set at $p < 0.10$. Therefore age, gender, race group, religion, children and medical care were significant in this model. Only the selected independent variables were entered into the final model.

Table 6b: Multiple linear regression - Final model selection

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error				Lower Bound	Upper Bound
(Constant)	88.469	5.328		16.603	.000	77.999	98.939
Age (at last birthday)	.345	.178	.095	1.936	.053	-.005	.695
Gender_Female	4.318	1.555	.128	2.778	.006	1.263	7.373
Race_White	7.781	2.787	.143	2.792	.005	2.304	13.257
Race_Indian	6.450	5.714	.116	1.129	.260	-4.779	17.678
Race_Coloured	14.819	6.881	.092	2.154	.032	1.298	28.340
Religion_ChristianProtestant	-5.958	3.297	-.186	-1.807	.071	-12.436	.520
Religion_Catholic	-5.922	3.502	-.160	-1.691	.092	-12.803	.960
Religion_Hindu	-6.634	6.466	-.098	-1.026	.305	-19.341	6.072
Religion_Muslim	-6.988	6.196	-.076	-1.128	.260	-19.163	5.188
Religion_Other	-2.191	5.184	-.022	-.423	.673	-12.377	7.995
MedCare_Public	-4.241	1.556	-.134	-2.726	.007	-7.299	-1.184
MedCare_Other	.164	5.884	.001	.028	.978	-11.398	11.727
Children_1	-1.753	2.154	-.037	-.814	.416	-5.986	2.480
Children_2	-8.573	4.158	-.095	-2.062	.040	-16.744	-.403
Children_3	-3.073	11.423	-.012	-.269	.788	-25.518	19.373

Table 6b illustrates the selected variables from in the initial model, which were converted to dichotomous variables and inputted into the final regression model. The significance level of the final model was set at $p < 0.05$, therefore age, gender (male as the reference category), race (Black as the reference category), medical care (private sector as the reference category) and children are accepted as predictors in of behaviour intentions to participate in HIV prevention research. The reference categories were chosen as follows:

- **Gender:** the category *male* chosen as the reference category since males were found to be more willing to participate in the independent samples t-test above
- **Race:** the category *Black* was chosen as the reference category since Black students accounted for more than 50% of the study sample
- **Religion:** the categories of *atheist / agnostic* were grouped and chosen as the reference category to compare students who belong to a specific religious grouping and those that do not
- **Medical Care:** the category of *private health care* was chosen as the reference category in order to observe the effect utilization of public health care system has on the BI score
- **Children:** the reference category of 0 was chosen to observe the effect of the presence of children on the BI score

The predictors in the intention to participate in this regression model can be interpreted as follows:

- **Age:** For every year increase in age, the total BI increases by 0.345 therefore an increase in age shows a decline in intention to participate
- **Gender:** female total BI scores were 4.318 greater than males; therefore, males show a greater intention to participate.
- **Race:** for White students the BI score was 7.781 greater than Black students. Therefore White students showed lower intentions to

participate. Indian students were not significantly different from Black students in the model

- **Children:** women with 2 children had a total BI score of -8.573 lower than women with no children. Therefore women with 2 children had a greater intention to participate
- **Medical Care:** students accessing public health care had a total BI score that was 4.241 less than students accessing private healthcare. Students accessing public health care had greater intentions to participate.

Table 6c: ANOVA of the multiple liner regression (Final model)

Model	Sum of Squares	Df	Mean Square	F	Sig.
Regression	16574.148	15	1104.943	4.951	.000 ^b
Residual	105794.745	474	223.196		
Total	122368.893	489			

Table 6c illustrates the ANOVA of the final multiple regression model. The significance value is less than 0.05; therefore the final model is statistically significant denoting that the independent variables in the final model can explain some of the variance seen in behaviour intentions. In order to determine the amount of variability that the model explains, the R^2 statistic was calculated below

Table 6d: Model summary for final regression model

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.368 ^a	.135	.108	14.940

Table 6d illustrates the results of the model summary for the final regression model. The adjusted R square value of this model indicates that only 10.8% of the variability seen in this population can be attributed to the predictors measured in this regression model, denoting that there are other variables, not

accounted for in this study that could influence the total BI score. This means that the demographic variables assessed in this study alone cannot explain these differences. Other variables that potentially influence behaviour intentions to participate in HIV prevention research, which is not assessed in this study, should be included in future research.

4.2.7. Confirmatory Factor Analysis (CFA)

This sub-section contains the results of the confirmatory factor analysis that was performed on the 8 factors making up the CRIS. The purpose of the CFA is to determine whether the data fits the model structure and if the model is adequate for this population.

Table 7a: Confirmatory factor analysis of the clinical research involvement scale - Unstandardized regression weights: (Default model)

			Estimate	S.E.	C.R.	P	Label
AttitudesScore	<---	Behaviour_Intentions	1.000				
SubjectiveNormsScore	<---	Behaviour_Intentions	.798	.050	15.930	***	
OrganizationInvolvementScore	<---	Behaviour_Intentions	.854	.054	15.795	***	
PersonalRelevanceScore	<---	Behaviour_Intentions	2.080	.111	18.749	***	
BehaviouralBeliefsScore	<---	Behaviour_Intentions	1.264	.083	15.263	***	
OutcomeEvaluationScore	<---	Behaviour_Intentions	-.673	.070	-9.646	***	
NormativeBeliefsScore	<---	Behaviour_Intentions	1.280	.088	14.582	***	
MotivationtoComplyScore	<---	Behaviour_Intentions	-.066	.085	-.782	.434	

Table 7a shows unstandardized regression weights for the 8 factors of the CRIS. All the observed variables except Motivation to Comply were significant at the $p < 0.50$ level.

Table 7b: Standardized regression weights: (Default model)

Observed Variables		Common Factor	Estimate
AttitudesScore	<---	Behaviour_Intentions	.735
SubjectiveNormsScore	<---	Behaviour_Intentions	.732
OrganizationInvolvementScore	<---	Behaviour_Intentions	.726
PersonalRelevanceScore	<---	Behaviour_Intentions	.865
BehaviouralBeliefsScore	<---	Behaviour_Intentions	.702
OutcomeEvaluationScore	<---	Behaviour_Intentions	-.449
NormativeBeliefsScore	<---	Behaviour_Intentions	.671
MotivationtoComplyScore	<---	Behaviour_Intentions	-.037

Table 7b shows standardised regression weight estimates for the 8 factors of the CRIS. Since all observed variables were loaded onto a single common factor (behavioural intentions), then the standardized regression weights were interpreted as the correlation between the observed variable and the single common factor. The observed variables of attitudes, subjective norms, organizational involvement, personal relevance, behavioural beliefs and normative beliefs correlated strongly with behaviour intentions. Outcome Evaluation appears to have had an inverse correlation with behaviour intention. Motivation to comply had a poor correlation with behaviour intentions and is non-significant in the model.

Table 7c: Squared multiple correlations

	Estimate
MotivationtoComplyScore	.001
NormativeBeliefsScore	.451
OutcomeEvaluationScore	.201
BehaviouralBeliefsScore	.492
PersonalRelevanceScore	.748
OrganizationInvolvementScore	.526
SubjectiveNormsScore	.535
AttitudesScore	.540

Table 7c shows the squared correlation statistics for the 8 factors of the CRIS. The square multiple correlations (R^2) describe the amount of variance that the common factor (behaviour intention) accounts for in the observed variables. Personal relevance appeared to be the strongest predictor of behaviour intention, with behaviour intention explaining 74.8% of variance in personal relevance. Behaviour intentions accounted for 54% of variance in attitudes, 53.5% of variance in subjective norms, 52.6% of variance in organizational involvement, 49.2% of variance in behavioural beliefs, 45.1% of variance in normative beliefs and 20.1% of variance in outcome evaluation. The weakest predictor was motivation to comply which was non-significant in the model.

Table 7d. Chi square result (Default model)

Minimum was achieved
Chi-square = 149.804
Degrees of freedom = 20
Probability level = .000

Table 7d shows the results of the chi square test for model. The chi-square statistic assesses the magnitude of discrepancy between the sample and the fitted model. Therefore the null hypothesis would indicate that the sample is equal to the fitted model. The chi-square statistic is high and significant at the probability level of $p < 0.05$. This indicates the null hypothesis is rejected. However, this does not indicate a badly fitted model, since the chi-squared statistic is sensitive to large samples sizes and is nearly always rejected with large sample sizes, as it the case in this study with a sample size of 509.

Table 7e: Model fit summary

Model	CFI	RMSEA	LO 90	HI 90	PCLOSE
Default model	.919	.113	.096	.130	.000
Independence model	.000	.336	.322	.350	.000

Table 7e shows the model fit summary with the indices to measure goodness of fit of the data to the model. Since the chi-square statistic is sensitive to sample

size, other goodness of fit indices are used to assess model fit, such as the comparative fit index (CFI) and the root mean square error of approximation (RMSEA) index. The CFI is least affected by sample size. Ideally the CFI for a well-fitting model would be greater than or equal to 0.95. The CFI in this model is 0.919, which indicates a mediocre fit. This means that the data in this survey does not fit well with the model structure of the CRIS. The RMSEA index favours parsimony, in that it favours a model with the least number of parameters. Current cut-off values suggest that an RMSEA close to 0.06 (upper limit of 0.70) indicates a good fitting model. The RMSEA for this model is 0.113 indicating a mediocre fitting model, which is in alignment with the CFI result. These results could be due to the non-significance of motivation to comply in the model and low predictive value of outcome evaluation. This is substantiated by the CFI results when both motivation to comply and outcome evaluation are removed from the model, the CFI increased to 0.95, which is indicative of a well-fitting model. Therefore unlike the findings of Frew *et al* (2007) which showed the CRIS to be a good fitting model, in this student population, the model did not fit well until the variables of motivation to comply and outcome evaluation were removed.

4.2.8. Summary

The study sample was not fully representative of the study population in respect of the racial demographics since Black students were over-represented and Indian students were under-represented.

In respect of participant demographics the mean age of participants across all race groups was 23 years, with females comprising two thirds of the study sample. Protestant Christianity emerged as the most common religion amongst all race groups except Indian students for which Hinduism was the most common religion. Across all race groups the majority of students actively practiced their religion on a weekly basis. In respect of relationship status, the majority of students reported not being married but having partner that they do not live with. Black female students reported a 4-fold increase in pregnancy

compared to other race groups. As expected, the majority of students across all race groups were full-time students who were not employed. However, White and Indian students reported a greater percentage of part-time employment. The majority of Black students reported use of the public health sector whereas the majority of White and Indian students used the private health sector.

In respect of willingness to participate, the majority of students, irrespective of race, were willing to participate in HIV prevention research and displayed positive behavioural beliefs about participation. Willingness to participate was highest amongst males compared to females, except for Indian males.

Further to assessing willingness to participate, the survey explored factors that influenced behaviour intentions to participate in HIV prevention research by the use of 8 factors that make up the CRIS. These were assessed as described below. Barriers to participation in HIV prevention research suggested in literature, such as perceived benefit, time, risk and dislike of needles were not perceived by students across all race groups as barriers. Students across all race groups perceived approval and support of referent others towards their involvement and participation in HIV prevention research. Students across all race groups expressed that they were not highly influenced by peers and family expectations. Students across all race groups had positive attitudes towards HIV prevention research, the possible benefits of participation and HIV as a concern in the respective communities. Students across all race groups displayed positive perceptions towards being involved in a clinical research organization. Black students felt a sense of purpose, belonging and empowerment by being involved in HIV prevention research, compared with White and Indian students who were more neutral.

Even though there appeared to be consensus amongst race groups for most items assessed, the intensity of responses differed amongst race groups. To determine whether the difference in intensity was statistically significant an ANOVA was conducted. All factors assessed except motivation to comply

showed a statistically significant difference in responses. A further Bonferroni test for multiple comparisons was performed to determine in which race groups the difference lay. The differences were primarily between Black and White students or Black and Indian students. There appeared to be no difference between White and Indian students. In order to determine the influence of demographic variables on behaviour intentions to participate in HIV prevention research (defined by the 8 factors assessed in the CRIS), a multiple linear regression was performed. The multiple linear regression revealed that only age, gender, race, number of children and where students accessed medical care influenced behaviour intentions to participate in HIV prevention research. However, these variables only explained a minor portion of the variability seen in behaviour intentions to participate in HIV prevention research. Other variables not considered in this study might have been relevant.

In order to determine whether the CRIS in its current structure is relevant instrument for the data derived from this population, a confirmatory factor analysis was performed. The results revealed that the data has mediocre fit within the CRIS in its current structure. If the factors of motivation to comply and outcome evaluation are removed, this improved the fit of the model, such that the data fitted better in the absence of these factors.

Chapter 5: Discussion

5. 1. Introduction

Willingness to participate and factors affecting willingness to participate in HIV prevention clinical trials are particularly pertinent in light of the current generalized HIV epidemic in South African. South Africa is currently experiencing a hyper-endemic epidemic with greater than 15% of its population aged 15-49 being infected with HIV (38) and an estimated 10% of the population is infected with an incidence of 0.85% (10) . As a result, representation of this pertinent at-risk age group in HIV prevention activities is particularly important in order to curb this epidemic.

5. 2. Analysis of data

Willingness to perform a specific behaviour can be defined as a person's openness to opportunity (70). It classically involves little prior contemplation of the behaviour and its consequences (70). Willingness to participate in this study was defined by a single item in the CRIS which states: "*I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS*". The results of this item reveal that the majority of students (85.9%) across all race groups were willing to participate in HIV prevention research. This indicates that there was no racial difference in willingness to participate in HIV prevention research in this study population. These findings are similar to the findings by Barsdorf and Wassenaar (2005) that reported no racial differences in willingness to participate in future medical research. These findings are promising since literature suggests that the average age of sexual debut for both males and females is between 15 and 17 years of age. In a generalized epidemic, merely being sexually active puts young people at risk of HIV acquisition (71). Therefore, an assumption can be made that these students, with a mean age of 23 years in this sample, have been sexually active. The HEAIDS Study of 2008 indicated that 2.4% of university students were HIV

positive, and when stratified by age, 15.1% of students aged 25 to 34 years were HIV positive, therefore mirroring the national HIV prevalence (70).

Even though no racial differences were noted in responses on this single item, the survey racial demographics, when compared to the university population demographics, show an over-representation of Black students and under-representation of Indian students. It can thus be deduced that Black students showed a greater interest in participating in this survey on HIV prevention. Even though there was a high willingness to participate amongst all race groups which is not racially segmented, racial differences did exist in intentions to participate in HIV prevention research. Intentions to perform a behaviour are assumed to reflect motivational factors that underlie specific actions (70). This study also aimed to determine whether these motivational factors could affect intention to participate and ultimately affect willingness to participate in HIV prevention research. It was noted that race was a significant predictor ($p < 0.001$) of intention to participate in HIV prevention research in the multiple linear regression model.

The CRIS was used to determine whether there were racial differences in factors affecting willingness to participate in HIV prevention research. The CRIS was designed to measure a respondent's intent to participate based on 8 factors, namely attitudes, subjective norms, behavioural beliefs, outcome evaluations, normative beliefs, motivation to comply, organizational involvement and personal relevance. Each factor contains a subset of Likert scale items which when summed allow interpretation as to whether the factor is positively or negatively perceived. Summation of all factors provides a measure of intent to participate in HIV prevention research.

In respect of attitudes towards participation in HIV prevention research it was found that Black students differed significantly from White ($p < 0.001$) and Indian students ($p < 0.001$). Based on mean responses, Black students "agree" that HIV is a serious concern in their immediate community but White and

Indian students displayed a neutral response (*“neither agree/disagree”*). This finding illustrates racial variability in risk perception. Students across all race groups perceived a benefit from HIV testing within a HIV prevention study. However, based on mean responses Black students *“strongly agree”* compared to White and Indian students who *“agree”*. The intensity difference in mean response could mean that Black students perceived a greater benefit from HIV testing in HIV prevention research compared to White and Indian students. This illustrates that even though the epidemic is generalized, White and Indian students still do not perceive as great a personal risk of acquiring HIV compared to Black students.

Black students *“agree”* that they would benefit from medical care associated with HIV prevention research but White and Indian students displayed a mean neutral response (*“neither agree/disagree”*). Linked to this racially differential response, were the demographic findings that the majority of Black students (64.5%) reported utilization of the public health care sector services compared to 9.6% of White students and 12.7% of Indian students. The majority (over 80%) of White and Indian students reported utilization of private sector health care. The racial difference in utilization of the public and private health sector is evident in this sample. South Africa has a fragmented health care system split into the public sector and the private sector (72, 73). The country as a whole is currently facing many issues with underperformance of the public health sector (72). Human resource issues and poor management coupled with the burden of HIV and associated illnesses on the health system, have contributed to the current weakened state of the public health service (72). However, the private sector, which is accessed by higher socioeconomic groups, is reputed for world class facilities and care provision (73). As part of ethical considerations for biomedical HIV prevention trials, it is prescribed that at minimum, participants should have regular and supportive contact with healthcare workers and counsellors throughout the course of the trial (74). As a result, basic and on-going healthcare is provided to trial participants throughout the duration of the trial. A study by MacPhail *et al* (2012) (75), noted that the main reason for trial

participation was linked to seeking high quality health care. In settings where access to quality health services is an issue, altruism is not the primary reason for participation (75). MacPhail *et al* (2012) (75) suggest that access to healthcare was a driving factor for participation in clinical trials. This is further substantiated in the regression model where intention to participate in HIV prevention research was significantly higher in those accessing public health care compared to those accessing private healthcare. Since utilization of the private sector classically denotes better socioeconomic status, it can be inferred that White and Indian students fare better in terms of socioeconomic status compared to Black students whose needs to access better medical care might be a driving factor for participation in HIV prevention research.

Subjective norms in this study assessed the perceived support of family and friends towards participants' involvement and participation in HIV prevention research (8). Favourable social opinion of research involvement was theorized to increase participatory intention (8). In respect of subjective norms about participation in HIV prevention research, Black students differed significantly from Indian students ($p=0.01$). Mean responses indicated that Black students "agree" that most people who were important to them thought that they should participate in a HIV prevention effort compared to Indian students who displayed a mean neutral response ("neither agree/disagree"). This finding suggests that Indian students did not expect the same support as Black students in respect of participation and involvement in HIV prevention research. This finding could either be as a result of low perceived risk amongst Indian students which negates the need for participation or perhaps the risk of being perceived as sexually active is a deterrent.

In respect of behavioural beliefs, Black students differed significantly from White ($p<0.001$) and Indian ($p=0.040$) students. All race groups believed that HIV prevention research would benefit their community. However the intensity of the response differed in that Black students appeared to "strongly agree" compared with White and Indian students whose mean response was "agree". A similar

finding was seen in the responses to “*My actions can inspire others to act and my participation in a HIV prevention study would be very good*”. Furthermore, Black and Indian students “*agree*” that their involvement in this cause would improve their community’s trust in medical research, with White students displaying a neutral response (“*neither agree/disagree*”). This finding implies that there is a need in these communities to improve trust in medical research. The legacy of human rights violations towards people of colour during apartheid could have negatively impacted public perceptions of health practice and medical research in South Africa (6).

Outcome evaluations in this study assessed barriers to participation such as concerns related to time and trouble related to study participation, risk aversion and fear of needles (8). In respect of outcome evaluations, Black students differed significantly from Indian students ($p < 0.001$). Both Black and White students “*disagree*” that participation in HIV prevention research seemed risky with Indian students displaying a neutral response (“*neither agree/disagree*”). Therefore Indian students appeared to have a level of indifference or uncertainty with regard to the safety of HIV prevention research.

Normative beliefs in this study assessed participants’ beliefs about the effects of research on their community and how it influenced participatory intentions (8). In respect of normative beliefs, Black students differed significantly compared to Indian students ($p = 0.042$). Black, White and Indian students “*agree*” that their doctor, work colleagues, immediate family and important people in their life would approve of their involvement in HIV prevention research. However, responses for Indian students were more “*neutral*”. Therefore Black and White students preferred to believe that referent others in their community would support their participation in HIV prevention research but Indian students’ strength of belief was not as strong.

Motivation to comply was the theorized influence of family, friends and others on behavioural performance which would exert social pressure to act or engage

in avoidance or rejection of the opportunity to become a study volunteer (8). This factor did not yield a statistically significant ($p = 0.434$) difference in responses in respect of race. Therefore racial differences did not exist in respect of influence of family, friends or referent others on intent to participate in HIV prevention research. Students across all race groups did not appear to be swayed by concerns over peer perceptions or conforming to family expectations. Their responses indicated that their decision-making was individualistic rather than conformist. The greater self-agency displayed by these students should lead to greater participatory intention (8).

Organizational involvement measured perception of a clinical research site and the extent to which persons identify with its research agenda. Black students differed significantly in respect of organizational involvement compared to White students ($p = 0.029$). Black and Indian students “agree” that being active in a clinical research organization would help express who they are. However, White students expressed a more neutral response (“neither agree/disagree”). Black students “agree” that others would view them favourably if they volunteered for a study at a clinical research organization; however White showed a neutral response (“neither agree/disagree”). This indicates that Black students perceived being involved with a clinical research organization more favourably than White students.

Personal relevance of volunteerism may exert influence on behavioural intentions to participate in HIV prevention research. In respect of personal relevance of volunteerism, there was a statistically significant difference between Black students compared to White ($p < 0.001$) and Indian ($p = 0.002$) students. Black students expressed greater personal relevance towards volunteerism compared to White and Indian students. This could possibly be linked to Black students’ beliefs regarding risk perception. It was however promising that Black, White and Indian students all “agree” that their involvement would help advance and protect the rights of others and that

through support of this cause they would be advancing the public's health and well-being.

In addition to the 8 factors that make up the CRIS which were used to assess factors that affect behaviour intentions to participate in HIV prevention research, the survey also included a demographic component. This data was collected in order to determine whether racial differences existed amongst these demographic variables and whether these variables influenced intention to participate in HIV prevention research. Intention to participate in HIV prevention research is defined by the total score of the 8 factors and is referred to as the behaviour intentions (BI) score (8). The higher the BI score, the less intent there was to participate in HIV prevention research (8). The demographic component revealed racial differences in willingness to participate in HIV prevention research as defined by the BI score compared to the single question mentioned above to assess willingness to participate. The findings revealed that White students had lower intentions to participate compared to Black students. Even though differences existed between Black and Indian students when the 8 factors were assessed separately, once combined to derive the total BI score, Black and Indian students showed similar intent to participate in HIV prevention research. There is no comparable data to draw from in literature since the BI as defined by the CRIS has not been tested in this manner before.

Intent to participate in HIV prevention research in this study also declined with age ($p=0.05$) as shown in the multiple linear regression model, but no racial differences existed in respect of this demographic. In addition to age, gender played an important role in willingness to participate in HIV prevention research. Female participants accounted for two thirds (66.2%) of the study sample for this survey, which is fitting for our South African epidemic since females are disproportionately affected in terms of acquisition of HIV in South Africa. The results of a National population based HIV survey in 2012, presented by Dr Olive Sishana, indicated that females have a higher prevalence of HIV infection across all ages groups compared to males (76). Sishana quoted that "*The*

disproportionately high HIV prevalence levels amongst young females in the country, however, requires a rethinking of conventional approaches to HIV prevention that addresses the underlying socio-cultural norms..."(76) Therefore female representation in this survey assists in determining how willing young females are to participate in HIV prevention studies, especially since many HIV prevention studies are female specific, such as microbicide clinical trials. The development of microbicides was to address gender power relations amongst heterosexual couples and provides a method that females can use covertly if they are unable to negotiate condom usage with their partners which is a reality for many women who are financially dependent on men (30). In this survey Black males (92.1%) and White males (92.9%) displayed greater willingness to participate in HIV prevention research as compared to Black females (82.5%) and White Females (78.8%). However, Indian females (91.7%) displayed greater willingness to participate in HIV prevention research compared to Indian males (77.8%) but this result could be attributed to the unequal sample size between these two groups. The gender difference was statistically significant ($p=0.004$). The regression model further substantiated this finding as gender was a significant ($p<0.001$) predictor of participation in the model. Enrolment statistics by gender of the HVTN 503 (Phambili) study showed that 55.1% males were enrolled compared to 44.9% of females in that study (28). These statistics are interesting to note since even though females displayed higher prevalence of HIV, males were more willing to participate in HIV prevention research, except Indian males. This could be as a result of lack of awareness of the current alarming statistics. However, it is promising that young Black and White males are taking an interest in HIV prevention. It would be important to determine why Indian males were less willing to participate in HIV prevention research compared to their Black and White counterparts.

The majority (81.0%) of female students across all race groups reported no pregnancies. However, the proportion of Black female students that reported one pregnancy (12%) was 4-fold higher than White and Indian female students. It must be noted that 96% of Black female students who reported one

pregnancy were unmarried. In the preceding 5 decades, both teenage and premarital pregnancy have become a norm for black women (72). The proportion of pregnancies can be seen as an indicator of unprotected sexual activity and possible low adherence to oral contraception. This pregnancy statistic observed transcends to the demographic variable of "*number of children*", in that it mirrors the statistics for women who reported having one child. However there was no racial difference in the proportion of female students who reported having two children. The regression model indicated that females who had two children had greater intentions to participate compared to females who had no children. This could possibly be tied in with a greater sense of preserving health due to having dependents; hence these women would be more inclined to seek good health care and would have a greater interest in preventing infection.

The majority (94%) of the survey respondents were unmarried. Fewer than 10% were married, with over 50% of students across all race groups reporting being in a relationship. The results of the National Population HIV survey in 2012 revealed that HIV amongst unmarried individuals is twice that of married individuals (76). This was correlated with unmarried individuals having a greater likelihood of reporting multiple sex partners in the preceding 12 months (76). This survey revealed that 25% of White students and 34% of Black students were currently unmarried and cohabiting with their partners. Further 7.27% of Indian students, 5.77% of White students and 4.73% of Black students reported having casual sexual partners. Cohabiting is viewed as a risk factor for HIV acquisition as literature suggests that condom use amongst couples who cohabit is lower, with resistance from males in these partnerships and also as a result of cultural norms (77). Resistance to condom use amongst cohabiting couples can be attributed to the association between condom use and lack of trust (77). However, many infections occur in these relationships either as a result of infidelity or unknown prior infection by one partner (77). Even though the statistics reveal that casual sexual partners were low within this population, their existence was still present, therefore the risk was present. The level of risk

associated with casual partnerships is dependent on whether the individual has repeated or once-off contact with casual partner/s and if the individual has multiple concurrent casual partners (78). Another important factor associated with casual partners is the abuse of alcohol and drugs (78). Unfortunately, this survey did not address these factors. Relationship status does have an influence on the level of risk exposure but it was not identified as a predictor of intention to participate in HIV prevention research.

According to the *National Guidelines for Payment of Participants in Clinical trials*, trial participants should be reimbursed for their time, travel and inconvenience (79). In South Africa, the Medicines Control Council (MCC) recommended that trial participants be reimbursed a minimum of R150 per trial visit (79). However, the National Health Research Ethics Council (NHREC) suggests that participants be reimbursed according to time, inconvenience and expenses incurred (79). In lower and middle incomes countries, there is a concern that reimbursement may be a driving factor for trial participation (75). The majority (over 80%) of the students in this study were full time students across all races. However, a greater proportion of Black students (80.28%) reported being unemployed compared to White (48.08%) and Indian (67.27%) students. There was a greater proportion of part-time employed White (34.62%) and Indian (23.64%) students compared to Black students (14.00%) and full-time employed White (17.31%) and Indian (9.09%) students compared to Black students (4.34%). Recent literature in South Africa states that financial status is a major HIV risk factor for HIV infection (80). Therefore students who are from economically and socially disadvantaged backgrounds are at higher risk of HIV infection (80). Students who are reliant on bursaries which are often not distributed until well into the academic year will experience financial difficulties (80). As a result, some female students engage in unwanted sexual practices for financial benefit (transactional sex) (80). Literature has suggested that “sugar daddies’ and prostitution have been seen in South African student populations (80). Even though employment status, which predicts financial

status, is a risk factor for HIV, in this population it did not appear to have an influence on intention to participate in HIV prevention trials.

There has been recent interest in the role that religion plays in response to the HIV epidemic in sub-Saharan Africa (81) due to the high level of religious involvement in this region (82). To this end the University of KwaZulu-Natal has established the Collaboration for HIV and AIDS and Religions and Theology (CHART) to better understand this interaction. In a study by Agardh *et al* (2011) (82) on sexual behaviour amongst Ugandan university students, religion emerged as an important determinant of sexual behaviour. Catholics are known for their strong stance against the use of condoms and oral contraception to prevent conception. Many HIV prevention clinical trials promote condom use and provide condoms to participants as part of a comprehensive package of prevention. Also some HIV prevention trials require female participants to be on oral contraception to prevent pregnancy since the effects on the foetus of certain research products have not been determined. Since the use of both condoms and oral contraception are prohibited in this faith, this could possibly affect intention to participate in HIV prevention research. The majority (54.5%) of survey respondents were Protestant Christians of various denominations and the results indicated that across all religions and race groups, the majority of students were willing to participate in HIV prevention research. Students across all race groups displayed a neutral response to the item "*If my religious leader supported HIV prevention research, I would be inclined to get involved.*" Hence, religion and the influence of a religious leader on decision making was not a predictor of participation in this population, which is further revealed by the lack of statistical significance of the religion variable in the regression model for behaviour intention.

The CRIS was deemed a reliable instrument in this study with a Cronbach's alpha statistic of 0.90. However, the confirmatory factor analysis which measures structure validity indicated that in its current structure, the CRIS had a

mediocre fit to the data from this population. Removal of the outcome evaluations and motivation to comply improved the fit of the data in the model.

5. 3. *Limitations*

5. 3. 1. Selection bias

The selection bias affecting this study can be described as under coverage / volunteer bias. Under coverage bias occurs when certain members of the population are not represented sufficiently within the study. In order to reduce this bias the request for participation was placed in a central location that all UKZN students could access. However, minimal under coverage bias was present in that Indian students were under-represented by 17% in this study and Black students were over-represented by 18%.

Also, only UKZN students were selected for participation in this study, therefore these results might not be generalizable to students from other institutions.

5. 3. 2. Confounding

Since an incentive was provided in this study in the form of survey participants being entered into a draw for two mall vouchers, socio-economic status, which was not assessed in this study, could have been a confounder to participation in this survey. Also as a result of the incentive, and given that the survey was conducted online, the same student could have done the survey more than once.

College / Discipline of study was also not included in the demographics section, and could also be a confounding variable in respect of interest to participate in this survey, since students from different fields of study might possess differential knowledge and interest in HIV prevention.

Chapter 6: Conclusions and Recommendations

6. 1. *Introduction*

Students across all race groups are willing to participate (85.9%) in HIV prevention research. However when assessing factors that could influence intentions to participate, racial differences were evident. This was largely as a result of differing perceptions of risk and social influences.

6. 2. *Conclusion*

When assessing willingness to participate superficially defined by a response to a single question in the CRIS, no statistically significant racial differences were noted. However, when assessing factors which influenced intent to participate as defined by the CRIS, Black students appeared to have greater intention to participate in HIV prevention research compared to White students. Indian students did not differ in respect of intention to participate compared to Black students. However, Indian students were under-represented in this study. With increased representation, this observation might change since under-representation might indicate a lack of interest in HIV prevention. Risk perception and necessity for access to better quality healthcare (itself a possible proxy for socio-economic status) were important factors that distinguish racial differences in intentions to participate and ultimately willingness to participate.

The CRIS was deemed as a reliable instrument in this population. However, in respect of validity, the CRIS in its current structure did not show strong validity. When modified by the removal of the factors of motivation to comply and outcome evaluations, validity improves in this population.

6. 3. *Recommendations*

Since this study was only conducted with students at the University of KwaZulu-Natal, expanding this study to other tertiary and post-secondary institutions would be beneficial to improve generalizability and in determining the validity of CRIS for this population. An expansion of demographic variables would be beneficial, such as relationship status, condom usage, socio-economic status and field of study. Further research should be conducted in respect of race group specific HIV risk perceptions, especially amongst Indians and Whites, and why females were in general less willing to participate in HIV prevention research compared to males, since they are a pertinent target group of HIV prevention initiatives.

It must be noted that this study could not explore the reasons for the responses provided by the participants and that the findings from this study would benefit from further qualitative research.

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Appendices

Appendix 1: Measurement Instrument

SECTION 1: Demographics

This is just to collect some basic background information. None of this personal information will be available to anyone other than the researcher.

Age (at last birthday) <input type="text"/>
Gender <input type="radio"/> Female <input type="radio"/> Male
* Race Group Choose one of the following answers Please choose... Please choose... Black White Indian Coloured Other:
Religion Choose one of the following answers Please choose... Please choose... Atheist Agnostic Christian (Protestant) Christian (Catholic) Hindu Muslim Other:
Religion - Frequency of Practice Choose one of the following answers Please choose... Please choose... Weekly Monthly During Festive Season Not Practicing Other:
? How often do you attend your religious institute
Relationship Status Choose one of the following answers Please choose... Please choose... Not married and no partner Not married but has a partner that does not live with me Not married but has a partner that lives with me / I live with Not married but I have casual partners Married Separated Divorced
Pregnancies Choose one of the following answers Please choose... Please choose... 0 1 2 3 4+
? How many times have you been pregnant

Children

Choose one of the following answers

Please choose... ▼

Please choose...

0

1

2

3

4+



How many children do you have

Student Status

Choose one of the following answers

Please choose... ▼

Please choose...

Full Time

Part Time



Are you registered on a full-time or part-time basis

Employment

Choose one of the following answers

Please choose... ▼

Please choose...

Full Time Employment

Part Time Employment

Not Employed



Are you employed and on what basis

Education (Highest Level Completed)

Choose one of the following answers

Please choose... ▼

Please choose...

Matric

Diploma / Certificate

Degree (1st Year)

Degree (2nd Year)

Degree (3rd Year)

Degree (4th Year)

Postgraduate (Honours)

Postgraduate (Masters)

Postgraduate (PHD)

Medical Care

Choose one of the following answers

Please choose... ▼

Please choose...

Public Sector

Private Sector

Other:



Where do you seek medical care from

SECTION 2: Clinical Research Involvement Scale

Background Information:

HIV Prevention Research Trials includes vaccines research, research into gels can be applied to the vagina, rings that can be inserted into the vagina and anti-retroviral drugs that can be taken to prevent HIV.

Instructions:

There is no right or wrong answer. We would like know how you honestly feel about each statement expressed. For each statement you have an option of *strongly agree (SA)*, *Agree (A)*, *Neither Agree or Disagree (N/DK)*, *Disagree (D)* and *Strongly Disagree (SD)*. Choose the answer that most appropriately expresses how you feel about each statement.

Behavioral Beliefs

	My community would really benefit from a HIV prevention research study	My actions can inspire others to act	My participation in a HIV prevention study would be very good	I benefit from health science research	My involvement in this cause will result in more ethical research	My involvement in this cause will improve my community's trust in medical research	I would participate in a HIV prevention research study because it would help to prevent HIV/AIDS
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Outcome Evaluation

	My participation in a HIV prevention research study would be more trouble than it's worth	Even if I wanted to participate in a HIV prevention research study, I just don't have the time	Participating in a HIV prevention research study seems risky	I would participate in a HIV prevention research study, but I don't like needles
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Normative Beliefs

	I think my doctor would approve of my involvement in HIV prevention research	I think my work colleagues would approve of my involvement in this cause	My immediate family is supportive of my involvement in HIV prevention research	Most people important to me think my involvement in HIV prevention research is good	Most people important to me usually support my interests	If my religious leader supported HIV prevention research, I would be inclined to get involved
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Motivation to Comply

	I tend to be concerned about what people think of me, even if I don't know them	I generally do what my family expects of me	I would not want to do something my friends disapproved of	If my superiors told me to do something I disagreed with, I would obey their wishes	Sometimes I do what my friends say to do, even though I know they are wrong
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Attitudes

	I like to do good for others	I like getting involved with HIV prevention research	HIV is a serious concern in my immediate community	HIV testing is a benefit of a HIV prevention study	I would benefit from the medical care associated with a HIV prevention study
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Subjective Norms

	Most people who are important to me think I should participate in a HIV prevention effort	Most people who are important to me would approve of my involvement in this cause	Most people who are important to me would support my interest in this cause
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Organization Involvement

	Being active with a clinical research organization would help me to express who I am	Hearing that somebody else is involved with a clinical research organization tells me a lot about that person	Others would view me favorably if I volunteered for a study at a clinical research organization
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Personal Relevance

	Being involved with a clinical research site helps me to feel empowered	I experience a sense of community in this cause	I feel a sense of belonging through my participation in this effort	My involvement is helping to protect the rights of others	I am advancing the public's health and well-being through my support of this cause	Getting involved in a HIV prevention effort is liberating	I feel a sense of purpose in this cause
Strongly Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Agree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neither Agree / Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strongly Disagree	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix 2: Online informed consent

Dear Student

My name is Diantha Pillay from the Department of Public Health Medicine at UKZN, Tel.: 031 260 1970, Email: pillayd33@ukzn.ac.za.

You are being invited to consider participating in a study that involves research regarding willingness to participate in HIV prevention research. The aim and purpose of this research is to determine student attitudes and beliefs in respect of willingness to participate in clinical research for HIV prevention. The study is expected to enroll a minimum of 447 students across all five campuses (Howard College, Westville, Medical School, Edgewood and Pietermaritzburg). There is no follow-up component to the study. Participation is once off at the time of answering an anonymous online questionnaire, which will take approximately 20 minutes to complete.

The study does not involve any risks and/or discomforts to you. The study will provide no direct benefit to you. However, scientifically the study will provide pertinent information on perceptions of novel strategies for HIV prevention.

This study has been ethically reviewed and approved by the UKZN Biomedical Research Ethics Committee (approval number BE094/11).

In the event of any problems or concerns/questions you may contact the researcher at Tel.: 031 260 1970 or email: pillayd33@ukzn.ac.za or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

Participation in this research is voluntary and refusal to participate will not have any implications on you.

There is no compensation to you however; all participants who complete the questionnaire will be put in a draw to win one of two R500 Pavilion Gift Vouchers.

All data obtained from the questionnaire is strictly confidential and will only be viewed by the researcher and authorized personnel for research purposes only. You are not required to include personal details (i.e.: name, contact number, address) on the questionnaire, hence you cannot be linked back to your questionnaire. The data obtained from the questionnaires will be retained in an online repository which has password restricted access.

If you wish to participate in this survey kindly complete the consent section.

Thank you

There are 22 questions in this survey

Informed Consent

Complete this section after you have read and understood the information sheet at the beginning of this survey. Select yes if you are willing to take this survey.

1 [0] I have been informed about the study entitled *Racial Differences in willingness to participate in HIV prevention clinical trials amongst University Students in KwaZulu Natal, South Africa in 2012* by Diantha Pillay.

I understand the purpose and procedures of the study.

I declare that my participation in this study is entirely voluntary and that I may refuse participation and bear no resultant implications.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at Tel.: 031 260 1970, Email: pillayd33@ukzn.ac.za or research supervisor at Tel.: 033 260 5373, Email: wassenaar@ukzn.ac.za.

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

*

Please choose **only one** of the following:

- ☐ Yes
☐ No

Appendix 3: Biomedical Research Ethics Committee (BREC) approval



RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Westville Campus
Gwen Abisi Building
Private Bag X 54001
Durban
4003
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 260-6609
Email: BREC@ukzn.ac.za
Website: <http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx>

Amended Letter
14 August 2012

Dr D Pillay
Department of Public Health Medicine
Nelson R. Mandela School of Medicine
University of KwaZulu-Natal

Dear Dr D Pillay

PROTOCOL: Racial Differences in willingness to participate in HIV prevention clinical trials amongst University Students in KwaZulu-Natal, South Africa
REF: BE094/11

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 03 June 2011.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 10 April 2012 to queries raised on 20 June 2011 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 14 August 2012.

This approval is valid for one year from 14 August 2012. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be RATIFIED by a full Committee at its next meeting taking place on 11 September 2012.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. Rambiritch', with a stylized flourish at the end.

Professor V Rambiritch
Deputy Chair: Biomedical Research Ethics Committee

Appendix 4: UKZN Registrar Approval



10 May 2012

Ms Diantha Pillay
School of Nursing and Public Health
Howard College Campus
UKZN
Email: 205518129@ukzn.ac.za

Dear Delia

RE: PERMISSION TO CONDUCT RESEARCH

Gatekeeper's permission is hereby granted for you to conduct research at the University of KwaZulu-Natal (ie to place a notice on the University website) towards your postgraduate studies, provided Ethical clearance has been obtained.

It is noted that the title of your dissertation is:

"Racial Differences in intention to participate in HIV prevention clinical trials amongst University students in KwaZulu-Natal, South Africa in 2012".



Please note that the data collected must be treated with due confidentiality and anonymity.

Yours sincerely



Professor J J Meyerowitz
REGISTRAR

Office of the Registrar
Postal Address: Private Bag X54001, Durban 4006, South Africa
Telephone: +27 (0) 31 260 8005/2206 Facsimile: +27 (0) 31 260 7824/2204 Email: registrar@ukzn.ac.za
Website: www.ukzn.ac.za

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Appendix 5: Scientific approval from UKZN Postgraduate Education Committee



14 September 2012

Ms Diantha Pillay
Student No 205518129
Discipline of Public Health Medicine
School of Nursing & Public Health

Dear Ms Pillay

PROTOCOL: *"Racial differences in willingness to participate in HIV prevention clinical trials amongst University students in KZN, South Africa in 2012"* D Pillay 205518129

Your protocol has been given final approval of the abovementioned study on 14th September 2012. This will be ratified at the next Postgraduate and Research & Higher Degrees Committee Meeting.

Please note:

- The Postgraduate Committee must review any changes made to this study.

May I take this opportunity to wish you every success with the study.

Yours sincerely

Mrs Devi Arumugam
Postgraduate Administrator
School of Nursing & Public Health

CC. Dr AS Voce
Public Health

**Postgraduate Administration
School of Nursing and Public Health
University of KwaZulu-Natal**

Postal Address: University of KZN, Durban, 4041, South Africa
Telephone: +27 (0) 31 260 2499
Facsimile: +27 (0) 31 260 1543

Founding Campuses:

- Edgewood
- Howard College
- Medical School
- Pietermaritzburg
- Westville