



Adapting an HIV Prevention Intervention for African Americans from the English Speaking Caribbean

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RESEARCH OBJECTIVES:

A. Background/Significance

HIV is a key area where health disparities among African Americans can be reduced. African Americans are (a) almost twice as likely as whites to have HIV; (b) experience higher rates of complications from the disease; (c) experience higher rates of disabilities from complications; and (d) have higher mortality rates (Kaiser Family Foundation 2008). Studies have found that (a) while Blacks represent 14% of Florida's adult population, they comprised 49% of the HIV/AIDS cases (FDOH, 2006); (b) The Caribbean represents the second highest HIV affected region in the world (UNAIDS, 2007); and (c) immigrants from the Caribbean region represent a significant proportion of those living with HIV in S. Florida. Moreover, although previous research has found that the impact of HIV stigma is different and perhaps more severe among Black individuals (Wingood et al., 2007; Rao et al., 2008; Moutsiakos & Chin, 2007; Emlet, 2007), culturally relevant solutions seem to elude health practitioners. Several studies have examined the relationship between stigma, disclosure and unsafe behaviors. Coping skills are also important and may vary across cultural contexts (Dageid & Duckert, 2008) as such as avoidance and escape, generally accepted as maladaptive, may be adaptive in certain societies.

While the effects of stigma have been related to reductions in physical, psychological and social functioning among a range of ethnic groups (e.g. Murphy, Austin, & Greenwell, 2006; Rao, Pryor, Gaddist, & Mayer, 2008; Diiorio et al., 2007), research has increasingly pointed to a differential and more severe impact on African Americans (Wingood et al., 2007; Emlet, 2007). Stigma has been related to higher levels of stress, suicidal ideation, a lower likelihood of seeking out medical care and higher levels of unprotected sex; it has also operated as a barrier to participation in interventions (Wingood et al., 2007; Foster, 2007). Several studies have examined the relationship between stigma, disclosure and unsafe behaviors. For example, stigma has been related to lower levels of disclosure and higher levels of unprotected sex (Wingood et al., 2007; Calin, Green, Hetherington, & Brook, 2007; Clark, Lindner, Armistead, & Austin, 2003). Disclosure itself has been associated with less unprotected sex and non-disclosure was related to having shorter-term relationships (Duru et al., 2006; Kiene et al., 2006). While the experience of stigma may be almost universal among persons living with HIV, as mentioned previously, there are elements of this experience that are particular to African Americans.

This proposed research study is significant for several reasons. First, it recognizes and responds to the alarming, and disproportionate impact of HIV/AIDS among Blacks. It is the fourth leading cause of death among Black men and the third among Black women aged 25-44 years old in the U.S. (CDC, 2007). In Florida, approximately 50% of the newly reported HIV/AIDS cases are among Blacks (Florida Department of Health [DOH], 2006). Given the

disproportionate impact of HIV on the Black population, there is a need for culturally sensitive interventions for this group. Second, although previous research has found that the impact of HIV stigma is different in the African American community, e.g. on health outcomes, nonparticipation in HIV vaccine trials, and responses to measure items (Wingood et al., 2007; Rao, Pryor, Gaddist, & Mayer, 2008; Moutsiakis & Chin, 2007), we are unaware of efforts to address and propose solutions for its impact that are specifically directed toward, and culturally relevant for, this population. Third, the relationship between stigma and non-disclosure of status has been well studied: however, the higher severity of impact of stigma in the African American community, the direct effects on non-disclosure, and the resulting behavioral consequences resulting in risky sex, have been understudied in this specific population. Fourth, while quantitative methodologies reveal a wealth of data, allowing for a better understanding of HIV, qualitative methods offer the possibility of filling gaps in our knowledge.

The Institute of Medicine (IOM) recommends the use of HIV prevention interventions with proven efficacy to avert new infections (IOM), and the Centers for Disease Control and Prevention (CDC) require CDC-funded health departments and community-based agencies to use evidence-based behavioral interventions (EBIs) defined as effective through the CDC's Synthesis of Prevention Research project (CDC, 2008).

The ADAPT-ITT Model

Wingood and DiClemente (2008) developed the ADAPT-ITT Model for adapting evidence based interventions (EBIs) in response to the time and cost associated with the development, implementation, and evaluation of efficacious HIV interventions. The ADAPT-ITT Model is a systematic framework that was developed to facilitate the efficient development of new EBIs. This model outlines a step by step process of how to modify existing models without competing with or contradicting its core elements. This model consists of three distinct phases, assessment, preparation and implementation with a series of specified action steps and eight phases. The ADAPT-ITT Model for adapting EBIs is versatile and when used as intended is applicable to diverse populations and settings, both nationally and internationally (Wingood, 2008). This study will focus on Phase one or the assessment phase of the ADAPT-ITT Model (Wingood, 2008), which is the formative evaluation of African Americans from the English Speaking Caribbean based on focus groups discussions identifying why this population is at risk for HIV. The main theme of the discussions will be identifying those HIV associated risks that differentiate the new target population (African American men and women from the English Speaking Caribbean) from the population on which the original EBI was developed. The team will review the discussions of the focus groups, and analyzed the results making necessary decisions that will inform the Decision Phase of the ADAPT-ITT model.

Goals:

The overall objective of this project is to assess the HIV associated behavioral and psychological risks of HIV-infected African American men and women over 18 years old from the English speaking Caribbean, their preference for intervention content and delivery and their perceived need for HIV prevention. The long-term goal of the proposed research is to guide the ADAPT-ITT model of adapting evidence-based interventions (EBI) aim at improving outcomes associated with reducing HIV transmission risk behaviors such as HIV perceived stigma, HIV sero-status disclosure and coping. The goals are:

1. To critically evaluate whether coping, disclosure, and/or stigma are associated with risky behaviors in HIV-infected African American adult men and women from the English Speaking Caribbean.
2. To assess HIV-infected African American adult men and women from the English Speaking Caribbean perceive HIV prevention needs and their preference for HIV intervention content and how they would like these interventions delivered.
3. To analyze the results of the focus group discussions, from which a draft document can be created to guide the decision phase of the ADAPT-ITT model of adapting an EBI. This decision phase closely examine the core elements of various EBIs appropriate for HIV-infected African American adult men and women and decide on which intervention to adopt or adapt.

SUBJECT RECRUITMENT:

A purposeful sample of approximately 50 African American men and women emigrated from about six (Jamaica, Trinidad, Tobago, U.S. Virgin Islands, Bahamas and Barbados) of the 23 English Speaking Caribbean countries will be recruited for this study. These participants will be registered patients over 18 years old receiving HIV medical, mental health or social services from the JTEOFHC. Participants will be recruited via an Institutional Review Board (IRB) approved flyer (Appendix A). Staff at the JTEOFHC will be informed of the study and will distribute flyers to all the units via their email listserv and unit staff meetings. In addition, approved flyers will be displayed in common areas such as waiting room, laboratory, pharmacy waiting area and registration areas where they could be readily noticed by staff and clients of the units. Approved flyers will contain the purpose of the study, the inclusion criteria, and the researcher's contact information. Interested participants will contact the PI. At this time participants will be pre-screened using a structured questionnaire (Appendix D), and appointments made for eligible participants.

Inclusion criteria include self-reported being from one of the English speaking Caribbean countries, being diagnosed with HIV, over 18 years old willing to participate in a research study and possessed a valid clinic card (indicating home unit). Home units are coded to indicate what services each patient is eligible for. Exclusion criteria would be clients who are unable to consent, who do not identify themselves as having been from the English speaking Caribbean or is HIV negative. Information obtained from databases will be limited to verification of being a registered patient of the Center HIV clinic. Viral load and CD4 count would not be considered, thus there will be no access of medical records.

METHOD AND PROCEDURES:

Methods

Morgan and Krueger's (1988) steps for data collection and analysis of focus groups will be followed rigorously to insure the accuracy and the credibility of the study findings. This method was selected because it was the suggested method that was used in the ADAPT-ITT model and other similar studies and it addresses the areas of inquiry from the participants' point of view. A purposive sample of African American men and women from English speaking Caribbean will be the sample for this study.

Sample/Sample Size with Rationale

The PI will conduct seven focus groups with 50 HIV African American men and women from the English speaking Caribbean, who have been a registered patient, 18 years and older who are receiving HIV related medical, mental health or social services from the JTEOFHC to address the major questions of the study. The participants will be recruited from the HIV clinics, of the Jessie Trice Economic Opportunity Family Health Center in South Florida, where these individuals are seen for routine HIV related medical, mental health or social services. The focus groups will be conducted at the community clinics. The PI chose to use a sample size of 50 because this allows for approximately seven focus groups and. The PI will be able to collect a range of data from these groups. According to Krueger (2000) focus groups should have 6-8 participants, representing a medium-level sample size. While it does not allow broad generalizations of this population, the number is large enough to allow key concepts and themes to arise as a result of the discussions as well as theoretical saturation.

Participants will be recruited to the study through these clinics. Because random sampling will not be possible with this sample, given the relatively small numbers, we will recruit the sample in consecutive fashion until the targeted numbers are reached. We anticipated that the study will span over a period of one year. Participants will be selected based on their willingness to participate in the study. Each focus group will comprise of 6-8 individuals. We anticipate conducting two focus groups for the males two for the females and three combined male-female groups. The focus groups will be conducted in a private room and male-female composition may vary depending on the preference of the participants.

Measures/Instruments - Demographic questionnaire

The demographics measure will be developed by the PI to collect basic background information on each participant. These items include age, gender, and ethnicity, years in the U.S, years since diagnosed with HIV, CD4 count and whether they are currently taking HIV medications.

Procedure

Before conducting the study, the entire study proposal will be presented for approval by the Florida International University (FIU) - Institutional Review Board. Upon board approval, the researcher will begin the study by distributing Institutional Review Board (IRB) approved flyers. These will be posted in areas where the HIV+ men and women will be able to see them. In addition, staff from the selected clinics will be informed of the study, and encouraged to hand out the flyers to their clients and inform them of the study. If an individual expresses interest in the study, they will be asked to discuss their participation in the study with the PI or her designate who will discuss purpose of study, date and time of focus group discussions. Each potential participant will be contacted prior to the schedule group discussion to confirm their attendance and their continued willingness to participate in the study. We will conduct seven focus groups with HIV infected black men and women from the English speaking Caribbean (new target population).

On the day of the focus group discussion, Informed Consents will be obtained before participating in the focus group, and the purpose of the study will be explained. Participants will be reminded that, participation in the study is voluntary, and permission to audio-tape the focus group discussions will be obtained. A short demographic questionnaire will be administered,

prior to the beginning of the discussion of the focus group, to allow us to report on basic demographic variables in order to better enable us to interpret some of the findings we expect to discover during the course of the groups. Participants will be reminded of confidentiality, the individual's ability to decide at any point not to participate, and the importance of their input will be explained.

Each group will be composed of 6-8 individuals and will be a representation of the proposed target population. Focus groups will be 60-90 minutes in length, and will focus on issues suggested by the literature to be of importance to these groups and the core elements of the EBI. The questions will cover stigma, disclosure, adherence and risky behaviors. The focus groups will begin with an introduction of why we are conducting the groups, an introduction of the facilitator and the note-taker, and finally, an introduction of the participants. An ice-breaker procedure is planned to encourage comfort with the team and with each other. The discussion will begin with the less sensitive questions and progress to more sensitive ones. All participants will be encouraged to speak, and we will use the techniques of motivational interviewing to elicit accurate and honest responses from the participants. The focus groups discussions will be audiotaped and transcribed verbatim.

The main concern in the administration of the focus groups will be the issue of maintaining confidentiality with this sample of men and women living with HIV. Extensive efforts will be made to ensure that the identities of the participants and the data collected will remain confidential. Participants will be assigned identification numbers to reduce the likelihood that responses are linked with specific individuals. Consent material will be kept in locked cabinets and will be kept separately from the collected data. Data forms, including demographics questionnaires, will have no identifying information.

The focus groups will be conducted by the principal investigator of this study and a research assistant. The assistant will assist in administering the demographic questionnaires, take notes, as needed, and generally assist in the facilitation of the focus groups. Prior to the focus group, the assistant will be trained in focus group procedures, confidentiality procedures and note-taking. The groups will be audio-taped, transcribed verbatim and analyzed for content and themes. Results of the thematic analyses of the groups will assist in the design of a series of drafts that will lead to the development of a culturally appropriate HIV EBI for African American HIV infected men and women from the English speaking Caribbean.

Plan for Data Analysis

The focus groups will be audiotaped, transcribed verbatim, and coded by the PI and the research assistant. Full text transcripts will be analyzed using Krueger's (1998) framework analysis of focus group which will occur concurrently with data collection and includes raw data, descriptive statements and interpretation. Both manual and computer data analysis will be conducted by the principal investigator. Krueger's Focus Group Criteria (1998) will be used to assure accuracy, reliability and validity of results. This form of analysis will include a review of content and themes that will allow the categorization of findings into thematic content areas covering stigma, disclosure, coping and will also allow for the discovery of other. The main themes/concepts will be reviewed by five focus group participants who will be asked to comment on the findings of the research study. Data related to socio-demographic variables will be analyzed using SPSS (version 14.0) to examine correlations / relationships among demographics such as age, level of education, length of time since diagnosis with HIV, and gender.

BENEFITS:

There are no direct benefits to individuals participating in this study. However, participation may help the investigators better understand how African Americans from the English speaking Caribbean who are infected with HIV perceived their HIV prevention needs and their preference for HIV intervention content and delivery . It will also assist the researchers. Results of the focus group discussions will also assist in the creation of a draft document to guide phase two of the ADAPT-ITT model of adapting an EBI.

RISKS TO SUBJECTS:

In research there is always some risk of breaching confidentiality; however, information gathered will be maintained in a confidential manner and steps to minimize breach of confidentiality will be taken. This researcher does not anticipate any risk of breach of confidentiality. If participants should become uncomfortable with the questions, they may stop at any time without any negative consequences. They can also refuse to answer any questions. There will be no personal identifiers, and any reference in transcripts will be by fictitious names. The only other potential risk to participants is a loss of personal time and inconvenience.

Minimal anticipated risks from participating in this study include the potential likelihood of anxiety, embarrassment, or discomfort resulting from discussing personal and sensitive matters. Prior arrangements will be made with the behavioral health clinic to provide participants with counseling if participating in the study were to cause any undue psychological stress or discomfort. The PI will conduct the focus groups and will be assisted by a registered nurse or an individual trained in conducting or recording focus groups. The JTEOFHC has a history of conducting small groups and provide routine behavioral services for HIV patients and have trained/experienced staff that will assist in data collection and the identification of group stress or discomfort. As a PMHNP, the PI will also be able to identify and refer any patient recognized with stress or discomfort.

INFORMED CONSENT:

Informed consent will be read verbatim at each focus group session by the PI At the time of completing the questionnaire, each participant will be given a letter explaining the study and will be asked to read and sign an informed consent that describes the purpose of the study, the potential risks and benefits, confidentiality, the right to refuse or withdraw at anytime without negative consequences and the data collection process. Each participant will be able to read and write English. Participants will then place a copy of the signed informed consent into a large, brown manila envelope and will keep one copy indicating that they agreed to participate in the study and that participation was voluntary. These participants will also be told that all data that identifies participants will be kept separate from the data and their responses will not be linked with their identity in any way.

CONFIDENTIALITY OF DATA:

Participant confidentiality will be maintained throughout and following the research project. Participants and groups will be assigned unique identifying codes, and all completed source documents will be transported, in a portable, keyed, solid-steel double-walled security chest with fire retardant insulation, measuring approximately 14 x 11 x 4 inches. Documents will then be filed and stored in a locked filing cabinet that is kept in a locked office in the College of Nursing

with access to the locked file cabinet only to the PI. Data collected will be destroyed using a shredder within ten days of completion of data analysis.

Data forms and data files collected will be identified by study ID number only. There will NOT be a list of subject names, ensuring anonymity. The study's PI and research assistants have completed the required training on research with human subjects. All persons who work on the project will be required to complete the NIH/OSRA on line training course. During presentation and publication of the study's findings, data will be reported in aggregate so individual respondents cannot be identified.

APPENDIX A

RESEARCH VOLUNTEERS NEEDED

WHO?

Clients from any English Speaking Caribbean country who have been diagnosed with HIV

Your Clinic Card is required

FOR WHAT?

To participate in a research study

Will take about 60- 90 minutes of your time

WHY?

To understand your experiences

Living with HIV and what services are needed to reduce the spread of the disease.

Contact:

Dr. Marjorie Gillespie-Johnson

Phone: 1-305-348-7722

Cell: 954-990-9993

You Will Be

Compensated

For Your Time!

APPENDIX B

PLEASE DO NOT WRITE YOUR NAME ON THIS QUESTIONNAIRE

DEMOGRAPHIC INFORMATION

Please answer each of the following questions

1. How old are you? _____
2. What is your gender? Male _____ Female _____
3. What is your marital status?
Single/Never Married _____ Separated/Divorced _____
Widowed _____ Married _____
4. What county do you currently
Live in _____
Work in _____
5. Where were you born?
Country _____ State _____
6. How long have you been living in the US? _____
7. What was the last grade education you have completed?
 - a) Primary/elementary _____
 - b) Secondary/Junior High _____
 - c) High School _____
 - d) 2 year college _____
 - e) 4-year college/University _____
 - f) Graduate School (Masters) _____
 - g) Doctorate (PhD/MD/Pharm D /DNS, Ed.D, etc)
8. What is your working Status?
Not Working _____
Part Time _____
Full time _____
9. Full + Part Time _____ What is your current annual income?

- \$15,000 or less _____
- \$15,001-\$30,000 _____
- \$30,001-\$45,000 _____
- \$45,001-\$60,000 _____
- Over \$60,000 _____
10. Where do you work? _____
11. What is your HIV status?
- HIV infected: _____
- AIDS: _____
12. What is your CD4 Count?
- Greater than 500 _____
- 350-500 _____
- 200-350 _____
- 100-200 _____
- Less than 100 _____ Don't Know _____
13. In what year were you diagnosed with HIV? _____
14. Are you taking or have you taken any HIV medication? _____

Appendix C

Letter of Explanation:

The following letter of explanation will be printed on FIU letter head and attached to the top of Demographic Questionnaire.

Dear _____

My name is Marjorie Gillespie, and I am an Assistant Professor at the Florida International University, Miami Florida. I am writing to ask you to participate in a research study.

The purpose of my research is to understand what are your experiences living with HIV and what are the services you need to help reduce the spread of the disease. You qualify for this research because you are from one of the English Speaking Caribbean countries and were diagnose with HIV.

This study will include your participation in a confidential group discussion of 6-8 people. We will ask you to tell us about your experiences living with the disease, what are some of the ways we can help you prevent the spread of HIV and how you think we can provide the services. The group may take about 60-90 minutes and will be held in a private location on a date and time convenient to you.

No risks are anticipated by participating in this study. Your participation will be confidential, and all of your responses will be reported as a group and not by individuals or names. Your decision to participate or not to participate in this study will not affect any current or future benefits or services you receive. You will not benefit directly from your participation in this study; however, the results of the study will assist researchers to plan suitable programs that are specific to the needs of HIV infected individuals from the English Speaking Caribbean. You will not be paid for your participation, but at the end of completing the discussion, you will be given a Wal-Mart gift certificate of \$20 as a token of appreciation for your participation.

If you do not wish to participate in this study, you may simply refuse and inform the researcher. If you would like to participate, or if you have any questions, you may contact me by telephone at the number on the flier or 954-990-9993 within the next week to arrange a convenient time and location. Your participation is entirely voluntary and you may withdraw from the study at any time.

Sincerely

Marjorie Gillespie, PhD, ARNP-C, PMHNP-BC
Assistant Professor

PRE- SCREENING QUESTIONNAIRE

1. How old are you? _____
2. What country were you born? _____
3. How many years have you lived in the U.S.? _____
4. Have you been diagnosed with HIV? _____
5. Where do you receive medical care/mental health or social services?

Appendix E - Consent Form



CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Adapting an HIV Prevention Intervention for African Americans from the English Speaking Caribbean

You are being asked to be in a research study. The investigator of this study is Dr Marjorie Gillespie Johnson and she is an assistant professor at FIU. The study will include about 50 people who are infected with HIV. Your participation will require approximately 90 minutes of your time. We are looking at the possible link between coping, disclosure of your HIV status, and/or stigma and how you feel this can help to prevent the spread of the disease.

If you decide to be a part of the study we will tell you what day and time to come to the health center conference room. You will be asked to complete a short survey. Someone at the meeting will explain to you how to complete the survey. You will be asked to answer general questions about: 1) your age; 2) your schooling; 3) your income; 4) what you think about your social life; and, 5) your current HIV status.

You will then join in a group discussion of about 6-8 people to discuss issues on HIV prevention. We will ask you what you think are the HIV prevention needs and what content you would you like and how would you like it to be delivered.

We do not expect any harm to you by being in the study. We would like you to participate in a frank open discussion, but you don't have to respond to every question. If you get upset or feel discomfort during the group discussion, you may ask to take a break. There is no cost or payment to you as a subject. You will not get any direct benefit from being in the study. However, your help will give us information about how people who are infected with HIV feel and what services they would like to prevent the spread of HIV. You will get a small gift as a token for being in the study.

Your answers will be identified by a random number and not your name. All of your answers are private and will not be shared with anyone unless required by law. Your data will be combined as a group and we will present the research results as a group. You may ask questions about the study at any time. If you choose not to participate no one will be upset with you. You may also choose to stop your participation before the group is completed. Even if you do not finish the group session you will get the gift.

If you would like more information about this research after you are done, you can contact me at 954-990-9993. If you feel that you were mistreated or would like to talk with someone about

Appendix F - Letters of Support