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An HIV/STI prevention intervention for internally displaced women in Leogane, Haiti: study protocol for an N-of-1 pilot study

Carmen H Logie,[1,2] CarolAnn Daniel,[3,4] Peter A Newman,[5] Mona R Loutfy[2]

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[1]Faculty of Social Work, University of Calgary, Calgary, Alberta, Canada
[2]Women's College Research Institute, Women's College Hospital, University of Toronto, Toronto, Ontario, Canada
[3]Faculty of Social Work, Adelphi University, New York, New York, USA
[4]NEGES Foundation, Leogane, Haiti
[5]Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, Ontario, Canada

Correspondence to
Carmen Logie;
clogie@ucalgary.ca

ABSTRACT

Introduction: Haiti has the highest HIV infection rate in the Western hemisphere, with approximately one in 50 people infected. The January 2010 earthquake led to the collapse of Haiti's social, economic and health infrastructure, exacerbating social and structural HIV risk factors. Internally displaced (ID) women are particularly at high risk for HIV infection due to breakdown of community networks, increased poverty and sexual violence. The authors present the rationale and study protocol for pilot-testing FASY (Famn an Aksyon Pou Santé Yo) (Women Taking Action For Their Health), a psychoeducational HIV/STI prevention intervention with ID women in Haiti.

Methods and analysis: This is a single-centre pragmatic N-of-1 pilot study. The target population is ID women in Leogane, Haiti. The authors aim to recruit 200 participants using purposive peer-driven recruitment methods. ID women will be trained as community health workers to deliver the FASY intervention in Kreyol. Participants will conduct a pretest that involves an individual HIV/STI educational video-based component followed by a 6-week group programme of 2 h women's health meetings. The primary outcome is HIV knowledge; our prespecified index of clinically significant change is an effect size of 0.30. Secondary outcomes include: sexually transmitted infections knowledge, condom use, social support, resilient coping, depression and relationship control. Multivariate analysis of variance will be used to compare pretest and post-test differences across variables to assess if the intervention influenced primary or secondary outcomes. Significant multivariate analysis of variance will be followed up with both univariate tests and discriminant function analyses to understand significant effects.

Ethics and dissemination: Research Ethics Board approval (2011-0033-E) was attained from the Women's College Hospital, University of Toronto, Toronto, Ontario, Canada. Trial results will be published according to the CONSORT statement, modified for the N-of-1 pilot study design, regardless of the outcomes.

Trial registration number: This study is registered at http://clinicaltrials.gov, registration number NCT01492829.

ARTICLE SUMMARY

Article focus

- Pilot testing of a psychoeducational HIV/STI prevention intervention for internally displaced (ID) women in Leogane, Haiti.
- Primary objective is assessment of changes in HIV knowledge among participants following intervention.
- Secondary objective is assessment of changes, compared with preintervention, in the following: sexually transmitted infections knowledge, condom use, social support, resilient coping, depression and relationship control.

Key messages

- There is a strong rationale for assessing feasibility through piloting this intervention as there is little known about women-focused HIV/STI prevention programmes in Haiti either prior to or following the 2010 earthquake.
- The results of this study may help to inform HIV prevention interventions among displaced women in Haiti and can be tested for applicability with ID women globally.

Strengths and limitations of this study

- First trial to develop and evaluate a community health worker-delivered psychoeducational HIV/STI prevention intervention among ID women in post-earthquake Haiti.
- Pragmatic design with inclusion of ID women as community health workers who deliver the individual- and group-focused intervention to other ID women.
- Single-centre study, non-randomised design and lack of control group could affect external validity.

INTRODUCTION

The public health importance of addressing HIV and STI prevention in Haiti

Haiti, the poorest country in the Western hemisphere, has the highest HIV infection rate in the region estimated at 1 in 50 people infected.[1] Like many Caribbean countries, heterosexual transmission accounts for most HIV infections.[2] Extreme poverty, lack of financial and human resources and HIV-related stigma[3] present challenges for Haiti in managing the HIV pandemic. Less than half (43%) of people living with HIV in Haiti have access to antiretroviral (ARV) treatment, and only 60% of HIV-positive women have access to ARV for preventing perinatal HIV transmission.[4] The deleterious impact of HIV and AIDS are further exacerbated by the January 2010 earthquake that led to the collapse of an already fragile social, economic and health infrastructure. Unicef[5] reported that 1 million people remained displaced 1-year following the earthquake, living in approximately 1200 internally displaced persons (IDP) camps. Despite high HIV infection rates prior to the earthquake, Unicef[5] noted that there is currently no organisation responsible for community-based HIV prevention, condom distribution or HIV education in IDP camps in Haiti.

Internally displaced (ID) women are particularly at high risk for HIV infection and sexually transmitted infections (STI) due to limited access to sexual and reproductive health services, the collapse of social infrastructure and community networks, increased poverty and sexual violence.[6–8] Even before Haiti's 2010 earthquake, women and girls were at higher risk for HIV infection due to social and structural factors, such as poverty and gender inequity.[9] Young women had lower levels of correct knowledge regarding HIV (34%) than young men (40%).[4] Low rates of HIV testing and condom use also pose significant HIV infection risks: only 8% of women and 5% of men in Haiti aged 15–49 years reported receiving an HIV test in the past 12 months and knowing their status[4] and most youth in a Port-au-Prince study had never used a condom.[10] Authors highlighted an acute need for HIV prevention services, with a particular focus on building self-esteem and sexual negotiation skills among young women.

One of the most prominent risk factors for HIV infection among women is the presence of an STI. Both the long-term effects of untreated STI and its connection to HIV among Haitian women are well documented.[10–12] Dorjgochoo *et al*[10] reported, for example, that among young adults in their study, women were twice as likely to have an STI than young men and people living with HIV were more than likely to have an STI than HIV-negative participants. A study focused on identifying chlamydia and gonorrhoea in a women's health clinic in rural Haiti recommended that STI prevention initiatives focus on encouraging STI testing, reviewing signs and symptoms of STI, and condom promotion and provision.[12] Given the high prevalence of STI and the relationship between untreated STI and HIV, HIV prevention efforts targeting Haitian women should simultaneously focus on STI prevention.

Previous HIV/STI prevention interventions in low resource settings recommend community-based approaches that address structural factors and social norms. Research has shown, for example, that involving local community-based organisations in the planning and delivery of HIV prevention interventions and strategies can facilitate their efficacy.[7 13 14] In their systematic review of HIV prevention, interventions for South African youth, Harrison *et al*[14] reported that interventions that focused on key structural factors such as gender equity, sexual coercion and economic factors appeared to have the greatest impact in reducing STI incidence and self-reported sexual risk behaviours.[14] Curriculum-based group interventions have also had positive outcomes in changing social norms related to HIV risk.[14] For example, a multicomponent youth-focused sexual health intervention in Tanzania that included community activities and peer sexual health education improved HIV knowledge and reduced reported STI symptoms.[15] In Malawi, a six-session peer group intervention for HIV prevention among rural adults was associated with increased positive attitudes towards condoms, increased self-efficacy for practising safer sex, increased partner communication and increased use of condoms in the past 2 months.[16]

There is an urgent need to address and understand HIV/STI risk and prevention in the context of sexual violence among ID women in Haiti.[17] One area of concern is the shortage of trained healthcare workers to provide HIV services: currently, Haiti is reported to have just 2.5 doctors and 1.1 nurses per 10 000 inhabitants.[18] The effectiveness of community health workers (CHW), members of a given community with limited training in comparison with other health professionals, in providing HIV-related services is well documented both in Haiti and in other low resource countries around the world.[9 18–21] Training and employing CHW also build capacity in the health workforce.

There is a scarcity of information regarding HIV prevention in post-earthquake Haiti. HIV prevention interventions prior to 2010 have focused on primary healthcare provision and capacity building in community health clinics. There is little known regarding efficacy of community-based CHW-delivered HIV/STI prevention psychoeducational programmes in the absence of widely available, accessible and affordable clinical health resources or systems—such as in Haiti's post-earthquake context.

Global HIV work with IDP has focused on measuring HIV incidence, distributing condoms or ARV distribution[22 23]—less research has focused on developing and evaluating cultural, gender and context appropriate HIV prevention strategies for ID women.[24] As there is a scarcity of literature regarding community-based psychoeducational HIV prevention interventions in Haiti, the

study design for this project is informed by prior research in Haiti and HIV/STI prevention interventions in sub-Saharan Africa. Many of the economic and social factors that affect HIV infection patterns in Africa are also pertinent to Haiti.[19] For example, struggles to meet basic needs for survival and sexual violence have been highlighted as drivers of HIV among IDP in Uganda.[25] There are over 1 million IDP in Haiti, and over 27 million IDP globally[26]: this study can therefore inform HIV prevention research/programming in Haiti and can be tested for applicability with IDP populations globally.

Rationale for assessing feasibility through pilot-testing

Working in collaboration with the NEGES Foundation, a community development organisation in Leogane, Haiti, we will develop and implement a CHW-delivered psychoeducational HIV/STI prevention intervention *FASY* (Famn an Aksyon Pou Santé Yo) (Women Taking Action For Their Health) that includes individual- and group-based components. There is a strong rationale for assessing feasibility through piloting this intervention as there is little known about women-focused HIV/STI prevention programmes in Haiti either prior to or following the 2010 earthquake.

We are carrying out this pilot study in order to: (1) understand feasibility of the research process, including recruitment and retention rates; (2) assess the resources (eg, time, budget) required for the implementing multiple components of the intervention, this is particularly salient in post-earthquake context in which there are limited health, social and infrastructure (eg, electricity) resources in Leogane; (3) understand management issues regarding data and personnel, including training needs among CHW and successful strategies at collecting and storing data; (4) assess scientific impacts, including pretest and post-test differences in primary (HIV knowledge) and secondary (STI knowledge, condom use, depression, social support, resilient coping and relationship control) outcomes; (5) assess and expand the intervention.

STUDY PURPOSE

The main purpose of the study is to evaluate whether, compared with preintervention, ID women who receive the FASY individual and group psychoeducational HIV/STI prevention intervention in Leogane, Haiti, will demonstrate increased HIV knowledge scores. The secondary objective was to assess if, compared with preintervention scores, participants who received the FASY intervention will demonstrate the following changes postintervention: (1) higher STI knowledge scores, (2) increased consistent condom use, (3) higher social support, (4) higher resilient coping, (5) lower depression and (6) higher relationship control. Study hypotheses include that, compared with preintervention, participants will demonstrate: higher HIV knowledge scores, higher STI knowledge cores, increased consistent condom use, higher social support, higher resilient coping, lower depression and higher relationship control, postintervention.

TRIAL DESIGN AND METHODS

Design

This is a single-centre pragmatic N-of-1 pilot study using a pre/post-test design.

Randomisation, allocation and blinding

Randomisation and allocation are not relevant due to the N-of-1 trial design. No blinding is being undertaken in this pilot study as it is an N-of-1 trial. Furthermore, as a pilot study, the feasibility, study procedures and documents are being assessed, which does not require blinding.

PARTICIPANTS

Research participants include ID women living in Leogane, Haiti. Participants will be recruited by trained CHW and NEGES community development agency in Leogane, Haiti. We aim to recruit a total sample of 200 women. Inclusion criteria for research participants include women aged older than 18 years who are: capable of providing informed consent; ID (defined as living in a tent, a camp and/or in a different location than they were living in prior to the 2010 earthquake) and interested in attending the 6-week programme of women's health discussions. Exclusion criteria include: below 18 years of age; does not identify as a woman; insufficient comprehension to provide informed consent; insufficient attention or interest to attend a 6-week programme of women's health discussions. CHW will include ID women (n=8) in Leogane, Haiti, who have high rates of literacy in oral and written Haitian Kreyol and experience conducting research and/or educational activities. CHW will be supervised by study coordinators based at the NEGES.

SAMPLE SIZE DETERMINATION

Sample size calculations were guided by the primary and secondary hypotheses and informed by previous HIV prevention interventions.[14] Our prespecified index of clinically significant change is an effect size of 0.30; the equivalent correlation for this effect size is 0.15, referring to a 15% difference in pretest and post-test scores. Sample size was calculated using G* Power 3.1. For multivariate analysis of variance (MANOVA) (repeated measures, within−between interactions), effect size: 0.30, error probability: 0.05, power: 0.90, number of groups: 2 (pretest and post-test), number of outcome measures: 7 (HIV knowledge, STI knowledge, condom use, depression, social support, resilient coping, relationship control), the total sample size: 200 are required.

RECRUITMENT

Survey participants will be recruited through trained CHW hired for the research study. Purposive sampling

methods will be used, specifically peer-driven recruitment (PDR). PDR involves direct contact between the CHW and the participant, recruitment from social networks and regulating the number of participants each CHW can recruit.[27] CHW will verbally disseminate information about the study and recruit a maximum of 25 participants. Limiting the number of participants each CHW can recruit will help to reduce bias. Peer to peer recruiting has been found to be an effective strategy to engage marginalised and stigmatised populations in HIV research and has been found to have positive effects with regard to informal peer education, health promotion and sharing of HIV resources.[28] PDR can also be used to disseminate research findings back to marginalised populations. Many potential participants have low literacy; thus no flyers or print advertising will be used. All recruitment will be conducted in Kreyol.

INTERVENTION

There are six components to the overall study:

1. Development of a survey to assess outcomes (HIV knowledge, STI knowledge, condom use, depression, resilient coping, social support, relationship control).
2. Development of a CHW training manual and HIV educational video in Kreyol.
3. Development and implementation of CHW training for ID women in Leogane, Haiti.
4. Implementation of a tablet-based pretest and post-test survey.
5. Implementation of a 6-week programme of psychoeducational sessions with ID women in Leogane, Haiti.
6. Implementation of a community forum including ID women to share basic HIV/STI information.

Survey development

Previous literature has highlighted high rates of HIV and STI and low HIV/STI knowledge among women in Haiti. The survey will be based on pre-existing scales with established reliability and validity and will be translated into Kreyol. We held two focus groups to pilot test scales, one with service providers (n=6) and another with CHW (n=8) in Leogane, Haiti. Each focus group was conducted in Kreyol and translated into English. Focus groups involved reviewing each survey item and outcome measure for its cultural, gender and contextual relevance for women in Leogane. Survey items were modified based on focus group feedback to enhance appropriateness. Participation in pilot testing was voluntary, and results will not be included in data analysis.

Development of a training manual and educational video

A training manual will be developed for CHW to guide weekly women's health meetings. This training manual will include discussion points, information and activities to guide each of the weekly women's health meetings. The manual will be primarily based on the Population Council's[29] 'It's All ONE Curriculum: A Unified Approach to Sexuality, Gender, HIV and Human Rights Education', designed primarily for sexuality/sexual health community educators. This curriculum has been tested cross-culturally and provides case studies from around the world as well as guidance on how to adapt the materials for use in different contexts.

Community health worker training

CHW will be considered employees and paid a rate equivalent to the hourly wage paid by the NEGES Foundation. We will hire CHW to conduct participant recruitment, pre/post-test survey administration and facilitation of weekly women's health meetings. We will develop and deliver a 6-day training for CHW that consisted of two components. The first component (2 days) will include basic research training: study design, confidentiality, ethics, informed consent, recruitment, survey implementation, facilitation skills for weekly meetings. The second component (4 days) will involve training CHW in the content areas for the weekly women's health meetings (HIV, STI, interpersonal relationships, communication and decision-making, mental health and well-being, coping). Training documents will be translated into Kreyol; the PI (CL) and coinvestigator (CD) in conjunction with a translator will conduct the training in Kreyol.

Pretest and post-test survey

A cross-sectional structured survey will be programmed on a tablet to be verbally administered by CHW (n=8) to 25 participants each. Benefits of verbally administered surveys include: enhancing accessibility to participants with differing levels of literacy, building trust between the interviewer and participant, and higher response rates.[30] We will provide training and written instructions for CHW to standardise the structured interviews. At the beginning of the interview, the CHW will describe the sections to be covered. Due to the sensitive nature of several topics (eg, sexual risk factors), participants will be informed that they have the option to fill out the tablet-based survey (either the entire survey or certain sections) independently if they wish and the CHW will guide the participant on which button on the tablet to press to respond and will be present to answer any questions. Buttons for certain questions pertaining to sexual risk factors were colour coded to facilitate participants to complete these items independently.

It will be stressed to participants that their decision to participate is voluntary and they can withdraw from the study at any time. Participants can also skip questions or entire sections. A brief HIV educational video (15 min in duration), reinforcing items in the HIV survey, will be programmed on the tablet and the participant and CHW watch the brief video together following survey completion. Participants will be provided with an honorarium for the pretest and post-test (equivalent to US$5 for each test). Participants will still be paid the full honorarium if they decide to not fully complete the survey.

Surveys will be implemented in a private room on the premises of the NEGES Foundation. Multiple strategies will be employed to protect confidentiality of participants. A significant part of the training for CHW will include confidentiality and ethics and each CHW will sign confidentiality agreements. No names or other identifying information will be collected on surveys or informed consent sheets; to enhance confidentiality, participants were instructed to sign with an X. Informed consent sheets and surveys will be kept at a locked filing cabinet at the NEGES. The surveys will include an ID number to compare pretest and post-test scores; the sheet with the ID number and participant's first name and last initial will be kept in a locked filing cabinet at the NEGES. The post-test will be conducted following the completion of the group interventions.

Weekly women's health meetings

Each CHW (n=8) will conduct a 2 h women's health meeting at the NEGES once a week for 6 weeks with 25 participants. Meetings will be held at the NEGES in a private room. Participants will receive an honorarium for each session attended, and food and refreshments will be provided. Weekly meetings will address the following content areas: (1) HIV and AIDS; (2) STI; (3) interpersonal relationships; (4) communication and decision-making skills; (5) mental health, resilience and coping; (6) creating community change. Limits of confidentiality will also be discussed with participants; in particular, participants will learn that confidentiality cannot be guaranteed during group meetings and to keep this in mind when they are sharing personal information. Sessions will be conducted in Kreyol, and CHW will record notes following each session regarding any questions or points that need clarification or issues that emerged in the group meeting. The coordinator and assistant coordinator will meet with the CHW weekly to provide support, clarification and any guidance requested.

Community forum

A community forum will be held at the NEGES in Leogane convening ID women, men and adolescents, social/healthcare providers, researchers and other stakeholders. The HIV educational video will be screened and HIV/STI knowledge questions that emerge within the consultations will also be addressed in this community forum. The UNAIDS IASC[6] highlighted that raising HIV awareness and fostering community support is an integral first step to addressing HIV in humanitarian settings.

OUTCOMES

Primary outcome

HIV knowledge will be assessed using the 18-item Brief HIV Knowledge Questionnaire.[31]

Secondary outcomes

STI knowledge will be assessed using five items from the Sexually Transmitted Disease Knowledge Questionnaire.[32] Relationship control will be measured using the 15-item Relationship Control subscale from the Sexual Relationship Power Scale.[33] Condom use will be assessed using 12 items that assess condom use with regular, casual, transactional and paid sex partners in oral, vaginal and anal sex.[34] Depression will be measured using the 7-item Beck Depression Inventory Fast-Screen.[35] The original Beck Depression Inventory Fast-Screen includes an item on suicidality that will not be included in this survey as the CHW may not feel adequately trained to cope effectively with a suicidal participant and may not have the resources to provide appropriate crisis management. Golden *et al*[36] reported that omitting the suicidality item did not impact its reliability and may in fact increase the acceptability of this tool to participants. Resilient coping will be assessed using the 4-item Brief Resilient Coping Scale.[37] The 12-item Multidimensional Scale of Perceived Social Support[38] will be used to measure social support.

FEASIBILITY CRITERIA

Feasibility will be assessed using the following criteria[39]:

Process: recruitment rates, refusal rates, retention rates for weekly women's meetings, eligibility criteria (sufficient/too restrictive), understanding of survey items, understanding of video.

Resources: length of time to fill out survey, availability of equipment needed for intervention, equipment broken or stolen, ability of software for capturing and understanding data, collaborating centre willingness and capacity, what components/resources could be added to strengthen the intervention.

Management: challenges the participating centre has managing the study, challenges experienced by study personnel, data collection problems, any important data not collected, problems managing the weekly health meetings, problems reimbursing participants and/or CHW.

Scientific: changes in primary or secondary outcome variables after participating in the intervention, estimated treatment effect, estimate of the variance of the treatment effect.

STATISTICAL METHODS

Descriptive analyses of socio-demographic (eg, age, income) variables, including means and SDs, will be conducted to provide an overview of participant characteristics. Second, items for each scale will be summed to calculate scores for HIV knowledge, STI knowledge, condom use, relationship power, depression, resilient coping and social support. Descriptive statistics will be calculated to determine frequencies, means and SDs for each summed score.

MANOVA will be used to assess pretest and post-test differences across outcome variables. Separate MANOVA analyses will be conducted for the primary outcome variable (HIV knowledge) and secondary outcome variables (STI knowledge, condom use, depression, resilient

coping, social support, relationship control). We will compare differences in participant scores from the pretest and post-test (post-test will be conducted following completion of the 6-weekly health meetings) to assess if the intervention influenced primary or secondary outcomes. We will conduct a multivariate analysis of covariance (MANCOVA) to control for the number of weekly health meetings attended. Significant MANCOVA will be followed up with both univariate tests and discriminant function analyses to understand significant effects. Discriminant function analyses can be used to identify variates (combinations of dependent variables) and how the dependent variables contribute to the variates. Analyses will be conducted using SPSS V.19 software. Cases with missing data will be omitted from analyses.

DISCUSSION

There is little evidence regarding community health worker-delivered psychoeducational HIV/STI prevention interventions targeting women in Haiti. Piloting studies provide multiple benefits such as: understanding the ability to recruit participants, assessing international collaborations and coordination for a clinical trial, evaluating the efficacy of an intervention in impacting outcomes, enhancing experience with the study intervention and determining feasibility and develop scale-up plans for phase III trials.[39] Limitations of this study include the single-centre non-randomised design and lack of control group; these factors could introduce bias and affect external validity. We will use this pilot study's findings to refine and modify methods for a larger scale study that integrates social, economic and technological components to promote health and reduce HIV risk among ID women in Haiti. Findings may also inform HIV/STI prevention interventions with ID women globally.

ETHICAL CONSIDERATIONS AND DISSEMINATION

This psychoeducational intervention poses minimal risks to participants; the primary risk will be breaches to confidentiality. Participants will have the option to complete the tablet-based survey privately to maintain confidentiality and privacy. To enhance confidentiality: CHW will be trained on ethics and sign confidentiality agreements; no names/identifying information will be collected on surveys or informed consent forms; and surveys/informed consent forms and surveys will be kept at a locked filing cabinet at the NEGES. Research Ethics Board approval (2011-0033-E) was attained from the Women's College Hospital, University of Toronto, Toronto, Ontario, Canada. This study is registered at http://clinicaltrials.gov, registration number NCT01492829.

PUBLICATION POLICY

The results of the trial will be published according to the CONSORT statement, modified for the N-of- 1 pilot study design. Regardless of the outcomes, trial results will be published a peer-reviewed scientific journal.

PROJECTED TIMETABLE FOR TRIAL

August 2011: study approved by the Research Ethics Board at Women's College Hospital, University of Toronto, Toronto, Ontario, Canada.

August 2011: survey translated and pilot-tested.

October 2011: CHW training manual developed.

November 2011: CHW trained.

December 2011: HIV educational video produced.

March 2012: participant recruitment and collection of pretest data completed.

May 2012: group intervention completed.

July 2012: post-test data collection and community forum completed.

August 2012: data entry and data cleaning completed.

September 2012: data analysis completed.

October 2012: article with study results submitted for publication in peer-reviewed journal.

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Contributors CL is the principal investigator, CD is the coinvestigator and PAN is the international mentor for the study. CL and CD conceived the idea for the trial. CL led writing the manuscript, CD contributed substantially to the writing of the manuscript. PAN and MRL contributed to the study design and methods. All authors reviewed the protocol.

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Competing interests None.

Patient consent A consent form that was approved by the Research Ethics Board was translated into Haitian Kreyol and signed with an X by participants to protect confidentiality and also to account for low literacy rates among women in Leogane, Haiti.

Ethics approval Ethics approval was provided by the Women's College Hospital, University of Toronto, Toronto, Ontario, Canada.

Provenance and peer review Not commissioned; internally peer reviewed.

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