Contemporary Clinical Trials Communications 29 (2022) 100980

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Adapting and pilot testing an HIV and intersectional stigma reducing intervention for Dominican Republic healthcare contexts: Protocol for translational research

Henna Budhwani [a,*], Robert Paulino-Ramírez [b], John Waters [c], Christyenne L. Bond [a], Ingrid Ruiz [b], Dustin M. Long [d], Nelson Varas-Díaz [e], Sylvie Naar [f], Laura Nyblade [g], Janet M. Turan [d,h]

[a] Florida State University, College of Nursing, Center of Population Sciences for Health Equity, Tallahassee, FL, United States
[b] Universidad Iberoamericana (UNIBE), Santo Domingo, Dominican Republic
[c] Caribbean Vulnerable Communities Coalition (CVC), Kingston, Jamaica
[d] University of Alabama at Birmingham, School of Public Health, Birmingham, AL, United States
[e] Florida International University, Department of Global and Sociocultural Studies, Miami, FL, United States
[f] Florida State University, Department of Behavioral Sciences and Social Medicine, Tallahassee, FL, United States
[g] Research Triangle Institute (RTI) International, Research Triangle Park, NC, United States
[h] Koç University, School of Medicine, Istanbul, Turkey

ARTICLE INFO

Keywords:
Stepped wedge randomized controlled trial
Implementation science
HIV
Stigma
Intervention
MSM
Transgender women
Clinic based

ABSTRACT

Background: This protocol details the adaptation and pilot testing of the Finding Respect and Ending Stigma around HIV (FRESH) intervention in Dominican Republic. FRESH is a healthcare setting stigma-reduction intervention designed to reduce stigmas affecting people living with HIV (PLHIV), focusing on HIV and intersectional stigmas experienced by sexual and gender minority (SGM) people living with HIV. After the successful adaptation of the FRESH intervention, it will be pilot-tested through the conduct of a pilot stepped wedge cluster randomized controlled trial.

Methods: Three aims are included in this study; Aim 1 includes exploratory qualitative assessment, specifically the conduct four focus groups with men who have sex with men (MSM) living with HIV (n = 24–32) and in-depth interviews with transgender women living with HIV to explore their experiences with stigma in clinics (n = 9–12). In-depth interviews will also be held with HIV healthcare workers to elucidate their perceptions and behaviors towards their SGM clients (n = 9–12). In Aim 2, informed by Aim 1 data, we will use the sequential phases of the ADAPT-ITT framework to iteratively adapt the FRESH intervention for the Dominican Republic. In Aim 3, the adapted intervention will be pilot-tested via a cluster stepped wedge randomized controlled trial to assess feasibility and acceptability of the intervention and study protocols.

Conclusions: If this pilot trial is successful, next steps will include testing the adapted intervention across Dominican Republic or in similar Spanish-speaking Caribbean nations in a larger trial to assess effectiveness in reducing stigma in clinical settings towards PLHIV.

1. Background

In Dominican Republic, stigma toward sexual and gender minorities (SGM), namely men who have sex with men (MSM) and transgender women, is commonplace [1–8]. Policies that perpetuate stigma towards people living with HIV (PLHIV) and SGMs are codified in local laws [1,2, 9–13]. Stigmatizing attitudes are reflected in the communication of healthcare workers; thus, stigma becomes embedded in the infrastructure of HIV clinics, causing PLHIV to be reluctant to engage in care due to fear of persecution [1–4]. In the local context of the Dominican Republic, PLHIV routinely experience intersectional stigma for living with HIV, identifying as a SGM, and in some cases for engaging in sex work

* Corresponding author. Florida State University, College of Nursing, Center of Population Sciences for Health Equity, 2010 Levy Avenue, Building B, Suite 3600, Tallahassee, FL, 32306, United States.
E-mail address: hbudhwani@fsu.edu (H. Budhwani).

https://doi.org/10.1016/j.conctc.2022.100980
Received 24 April 2022; Received in revised form 22 July 2022; Accepted 9 August 2022
Available online 19 August 2022
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and/or being a migrant [11,14–19]. This intersectionality may increase the amount and intensity of stigma experienced by SGMs who are living with HIV, with harmful effects on health outcomes [14–19]. Research shows that stigma is a significant barrier to HIV care and contributes to the Dominican Republic's low 16% viral suppression rate [1,20,21].

Consejo Nacional para el VIH y el SIDA (CONAVIHSIDA, National Council for HIV and AIDS) recently released results from its national Dominican Republic study on HIV stigma [2]. Findings indicated that over a third of healthcare workers had no stigma reduction training; a third of healthcare workers were afraid to draw blood from PLHIV, and 56% of healthcare workers did not want to provide services to SGM clients living with HIV [2]. Similar findings from the Transgender Health Study provide additional evidence that stigma is a significant barrier to HIV services in the Dominican Republic [11–13]. Stigmatizing attitudes from healthcare workers can push the epidemic underground and promote the spread of HIV, because PLHIV and SGMs may avoid engaging in care fearing stigmatizing attitudes from healthcare workers and therefore may run out of their antiretroviral medications or may be unaware of their viral loads [1–4,11,12]. It is imperative that tailored stigma reducing interventions for healthcare settings are developed and tested [22–24]. If HIV and intersectional stigmas are not addressed, Dominican Republic may see a rise in new infections and worsening of outcomes across the HIV continuum of care [2,11,25–29].

1.1. Finding Respect and Ending Stigma around HIV (FRESH)

There are few evidence-based HIV-related stigma reduction interventions for healthcare settings [5,9,16,29,30]. Those that do exist have primarily been developed for Asian and African contexts, making the adaptation of the FRESH intervention for the Spanish-speaking Caribbean particularly novel [31–33]. FRESH is a workshop based intervention that was developed for use in Africa, and thereafter was adapted for the local contexts of the southern United States. In assessing interventions for appropriateness, we applied Nyblade's [31] criteria for evaluating stigma-reduction efforts [34–36]. Criteria suggests that evidence-based strategies for reducing stigma in clinics should involve both PLHIV and workers, use participatory methods, address actionable drivers of stigma in the short term, put PLHIV at the core of the response, and create partnerships between PLHIV experiencing stigma and healthcare workers to model non-stigmatizing behaviors [31]. FRESH is one of the few interventions that meets these criteria, warranting adaptation for Dominican Republic.

The FRESH intervention brings together healthcare workers and PLHIV to collaborate in a workshop to increase understanding of HIV-related and intersectional stigmas [7,9,14–19]. FRESH facilitates conversations on effects of stigma on health and well-being and guides participants to better recognize and understand stigmas. FRESH includes didactic content and interactive activities. Each topic includes contact-theory informed activities designed to bring healthcare workers and PLHIV together to change perceptions of each other while enhancing empowerment and empathy [7,9,37]. Facilitators use a standard manual for consistent content delivery.

1.2. Study aims

In this protocol, we detail activities conducted with three study aims:

- Aim 1: Explore sources, characteristics, and consequences of HIV-related and intersectional stigmas experienced in healthcare settings by MSM and transgender women to inform the adaptation of FRESH.
- Aim 2: Adapt FRESH to address stigmas experienced by MSM and transgender women in Dominican Republic.
- Aim 3: Pilot-test the adapted intervention to obtain estimates of its ability to reduce stigmatizing attitudes and behaviors from healthcare workers and experiences of stigma reported by SGM and non-SGM clients living with HIV (primary), while exploring if FRESH has the potential to influence clinic-level HIV cascade outcomes.

2. Methods

2.1. Study design

Setting: The Ministry of Health (Ministerio de Salud Publica, MOH) is responsible for all health care in the Dominican Republic and supports a network of 1774 primary care units, 122 hospitals, and 80 HIV clinics. The MOH will support the testing of the adapted intervention at two government HIV clinics in Santo Domingo and Santiago: Centro Sanitario Dr. Galván, and Centro Policlínico Lotes y Servicios. Leadership at sites have agreed to participate and PLHIV will be recruited during events hosted by clinics or during their clinical visits.

Design: We will conduct a pilot cluster randomized stepped wedge trial with two sites, one in Santo Domingo and the other in Santiago, to reduce contamination risk. We will include a third clinic as an adaptation site that will not participate in the pilot testing of the intervention. Since FRESH is a clinic level intervention and outcomes will be evaluated at the clinic level (not patient level), workshop participants discussing FRESH with non-participants (same site) will not contaminate results, and in fact will enhance the anticipated outcomes.

Ethics: Approval for this study approval was provided by Universidad Iberoamericana Institutional Review Board (IRB), under study number: CEI2020-32 and the University of Alabama at Birmingham (UAB) IRB under number 300005657. Informed consent will be obtained from human study participants, and this protocol is in compliance with all guidelines outlined in the Declaration of Helsinki.

Allocation: At study initiation, we will assign our three sites to adaptation, first-receipt, and second-receipt. Aims 1 and 2 will occur at the adaptation site. Aim 3 includes FRESH delivery and examination of outcomes from first-receipt and second-receipt sites.

Translation: Although, the research team includes native Spanish speakers, we will engage an established consultant in Dominican Republic to support the translation of FRESH content, modules, facilitator guides, and stigma measures. We will use cultural translation [38,39] that includes back translation. Cultural translation considers cultural relevance in the translation process, in addition to making word-for-word matches [38,39].

2.2. Aim 1: explore sources, characteristics, and consequences of stigma

The study team will conduct in-depth interviews with healthcare workers, focus groups with MSM who are living with HIV, and in-depth interviews with transgender women living with HIV. Healthcare workers will include any staff who have routine contact (minimum of 4 h weekly) with PLHIV, including clinicians, receptionists, security guards, etc. Non-clinical healthcare workers can significantly influence a PLHIV's willingness to engage in care [40–43]; thus, inclusion of non-clinical healthcare workers will be imperative to stigma reduction efforts [40–43]. Focus groups and in-depth interviews with MSM and transgender women will include those who are 18+ years, speak Spanish, and live in Dominican Republic.

Focus groups and in-depth interviews: Four 1-h focus groups are planned with MSM living with HIV (N = 24–32), each including 6–8 MSM, but data collection will occur until we achieve saturation. We will solicit data on stigmas as barriers to care, resiliencies, and coping skills, and how to adapt FRESH for Dominican Republic contexts. One-on-one interviews with transgender women living with HIV (estimated N = 9–12) will last about 1 h. Interviews will cover topics included in the focus groups, as well as specific questions to elucidate personal stories such as: "Describe your experiences receiving HIV services, as a transgender woman." Interviews with healthcare workers (estimated N = 9–12) will last about an hour.

Qualitative data analysis: In-depth interviews and focus groups will

be audio-recorded using digital recorders; audio files will be uploaded to an encrypted password protected UAB server. Spanish audio files will be transcribed into Microsoft Word by an expert transcriptionist. Transcribed files will then be translated to English. Rapid Qualitative Analysis [44] will initially be conducted to identify information relevant to the intervention adaptation. Rapid Qualitative Analysis will be guided by a standardized questionnaire matrix focusing on key adaptation questions (e.g., preferred duration, location, etc.). Thereafter, leveraging a thematic analysis approach, formal coding and analysis will be conducted by two coders with representation from the United States and Dominican Republic [45], in which a priori themes and sub-themes from theory and literature are supplemented with emerging themes "grounded" in the data [46]. NVivo software will be used for coding and analysis. A preliminary coding scheme will be developed based on topics in the literature and guides and will be appended during review resulting in a refined coding scheme. Transcripts will be re-reviewed and more detailed, second-level fine coding will occur.

2.3. Aim 2: adapt FRESH to address stigmas experienced by SGM

ADAPT-ITT [47] is an 8-step guide for adapting HIV interventions. Adaptation is the process of modifying an intervention without contradicting its core logic [31]. Without attention to characteristics of a new setting, unadapted interventions may lack acceptability and relevance [47,48]. Given the cost to develop and evaluate interventions, using ADAPT-ITT is an efficient approach to scientific discovery [47]. Table 1 outlines ADAPT-ITT steps for FRESH.

After Aim 1 data are analyzed and pertinent themes are identified, these data will be used to inform the adaptation of FRESH. Format adaptations may include making FRESH longer or shorter in duration or adapting FRESH delivery to better accommodate the needs of MSM and transgender women experiencing intersectional stigmas. Content changes may include placing greater emphasis on masculine tones appealing to certain audiences or adding modules that are directly relevant to the unique experiences of stigma in Dominican Republic. After changes are made in English, the revision will be culturally translated to Spanish yielding Draft 1. Draft 1 will be shared with healthcare workers and PLHIV at the adaptation site using role play demonstrations. Afterwards, participants will provide their feedback on Draft 1. We will then take this feedback and create Draft 2. We will then convene healthcare workers and PLHIV at the adaptation site and present revised FRESH at an adaptation workshop that will mirror the final intervention for format, content, and delivery. Participants and facilitators will comment on the adaptation workshop. Once FRESH is finalized, selected facilitators (including members of the study team and SGM living with HIV) will be trained on the intervention. The local Co-Principal Investigator and Co-Investigator will monitor fidelity [49].

Table 1
Steps of ADAPT-ITT [47] for FRESH.

Phase	Tasks
Assessment	Conduct focus groups and in-depth interviews with PLHIV and healthcare workers
	Analyze the qualitative data collected
Decision	Decide how to adapt the FRESH intervention
Adaptation	Pre-test FRESH with PLHIV; feedback survey
	Pre-test FRESH with healthcare workers
	Analyze results of the survey data collected from healthcare workers and PLHIV
Production	Produce draft of the adaptation with process measures
Topic Experts	Share the adapted FRESH with study team and community partners
Integration	Integrate feedback from experts and create draft 2
	Test adapted FRESH with PLHIV and healthcare workers
	Integrate feedback into draft 2 of the intervention to create draft 3
	Adapt training manual and process files for the new FRESH
Training	Train local facilitators on FRESH
Testing	Conduct pilot study for feasibility and acceptability
	Collect satisfaction and preliminary effectiveness data
	Conduct a full-scale trial of FRESH (after the conclusion of this pilot)

2.4. Aim 3: pilot-test the adapted FRESH intervention

The pragmatic stepped wedge cluster randomized controlled trial design reconciles scientific requirements for robust assessment with logistical constraints and ethical considerations [50]. See Fig. 1.

Data: In Aim 3, there will be three forms of data collection: in-clinic survey data from PLHIV clients and clinic healthcare workers, pre- and post-workshop survey data from PLHIV clients and healthcare workers who are involved in the workshops, and clinic-level continuum of care outcomes for each clinic collected from the MOH.

In-clinic data: This data collection will begin before FRESH delivery at the first-receipt clinic and will continue until 3-months after FRESH delivery at the second-receipt clinic. Sociodemographics will be collected from healthcare workers and clients, including gender, sex assigned at birth, age, race or ethnicity, income, occupation, education, sexual orientation, transportation access, and self-reported health. We will also collect information on covariates, stigma-related measures, and HIV-related behavioral outcomes through Qualtrics questionnaires completed by healthcare workers and PLHIV in clinics on iPads. We will collect these data from all healthcare workers and PLHIV clients at participating clinics (not just those who attend FRESH workshops), since we expect the effects of FRESH will be experienced clinic-wide (Fig. 1). Estimating 50% response rate for clients and 80%+ response rate for healthcare workers, across 4 time points, we estimate samples of $N = 400$ PLHIV client surveys; $N = 80$ healthcare worker surveys.

Pre- and post-FRESH workshop data: Approximately 10 SGM PLHIV and ten healthcare workers from each site will attend each workshop. From participants, we will collect pre- ($N = 40$) and post- ($N = 40$) workshop surveys to assess satisfaction, feasibility, acceptability. Table 2 includes stigma and potential mediating and moderating measures to be collected in surveys pre- and post-FRESH workshop. All scales demonstrated acceptable internal reliability in the prior FRESH studies [9]. If a Spanish version of a scale is available, we will use it. Otherwise, we will have the scale expertly translated using cultural translation procedures [38,39].

HIV continuum of care data: Given that FRESH is a clinic-level intervention, we hypothesize it has the potential to positively influence clinic-level cascade outcomes. For intervention sites, HIV continuum of care data will be obtained from the MOH quarterly for the full 24-months of this pilot study. Data will include CD4 count and viral load suppression rates. Retention in care is not currently collected in this system. These data will be used to compare site-level HIV cascade outcomes pre- and post- FRESH.

Data analysis: Our analysis plan includes four steps: 1) Evaluate reliability of Spanish translated stigma scales; 2) Assess acceptability of the adapted intervention; 3) Analyze stigma and related constructs pre- and post-intervention and between intervention sites, and 4) Examine HIV cascade outcomes pre- and post-intervention and between intervention sites. To ensure reliability of newly translated stigma scales, we will calculate Cronbach's alphas [51] and compare the statistic for the Spanish version to published values for the English version. To examine acceptability of the intervention, we will analyze post-FRESH questionnaire data on workshop satisfaction from workshop participants [9] and examine open-ended responses using content analysis methods. Responses will be coded according to emerging themes and sub-themes in NVivo.

Using the in-clinic data, we will use descriptive statistics for stigma outcomes and potential mediators and moderators of interest. As this is a stepped wedge trial, we will apply generalized linear mixed models with random effects for sites and participants to compare changes over time, specifically changes from pre-FRESH (before stepping) to post-FRESH (after stepping). Data from all time points will be used to determine sustainment by estimating time trends. Baseline values will be entered as

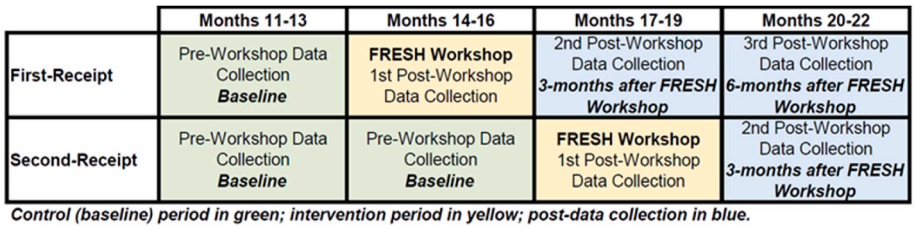


Fig. 1. Pilot stepped wedge design for FRESH pilot study.

Table 2
Measures to be collected pre- and post-FRESH workshop.

Construct	Scale	#
Healthcare Workers		
HIV stigma among healthcare workers	Measuring HIV Stigma and Discrimination Among Health Facility Staff [52,53]; Observed Stigma in Healthcare Facility, Opinions about PLHIV, and Anticipated Stigma	25
HIV knowledge	HIV Knowledge Questionnaire (HIV-KQ-18) [54]	18
Empathy for PLHIV	Jefferson Scale of Physician Empathy [55]	11
Perceived risk of HIV	Perceived Risk of HIV Scale [56]	10
Interpersonal contact	Social Distance from PLHIV, Social Distance Scale [57]	7
Self-efficacy for change	General Self-Efficacy Scale [58]	10
People Living with HIV (PLHIV)		
HIV-related stigma	HIV Stigma Scale [59]	
	Enacted Stigma, Disclosure Concerns, Negative Self-Image, and Concern with Public Attitudes	27
	Experienced Stigma in Healthcare Settings [52]	6
	HIV Stigma Mechanisms Scales [60]	
	Anticipated Stigma [61]	9
Intersectional stigma	Multiple Discrimination Scale [62]	10
Empowerment	Healthcare Empowerment Inventory [63]	8
Adherence self-efficacy	HIV Treatment Adherence Self-Efficacy Scale [64]	12
Self-esteem	Rosenberg Self-Esteem Scale [65]	10
Depression symptoms	Patient Health Questionnaire Scale (PHQ-8) [66]	10
Antiretroviral medication adherence	Antiretroviral Adherence Questionnaire [67]	3

controls. Analyses will be performed for healthcare workers and PLHIV separately and in aggregate. Estimates of correlations, intra-cluster correlation, within-period correlation, etc. will be calculated to inform future trial designs.

Power calculation: As a pilot study to develop preliminary estimates, this study is not powered to show efficacy.

Anticipated challenges and alternative approaches: We may face challenges in recruiting and retaining SGM living with HIV. To minimize this risk, we have engaged local civil society, advocacy, and community agencies; these agencies will help recruit and encourage participation in the study and suggest potential facilitators. We will collect multiple points of contact and seek consent to follow-up via text and calling from participants. We may find that low literacy levels warrant verbal informed consent. If so, we have successfully employed verbal consent with protections for maintaining in prior global HIV studies [13]. The extra attention paid to stigma reduction in this trial may reduce stigma due to a Hawthorne Effect, and participants may be influenced by social-desirability bias in their self-reported responses.

3. Results

This study was funded during summer 2020. Approval from Universidad Iberoamericana (UNIBE) UAB IRBs were obtained shortly thereafter. Aim 1 data collection concluded in 2021. The entire study is expected to be completed at the end of 2022.

4. Discussion

Because FRESH will be adapted for the Spanish-speaking Dominican Republic, it could be extensible to other Spanish-speaking contexts in Latin America and the Caribbean. By testing the reliability of Spanish-translated stigma scales, a stated National Institutes of Health/Fogarty International Center priority, findings could advance the field of stigma measurement. By using a pilot stepped wedge cluster randomized control trial, we employ a design that ensures all sites receive this stigma-reducing intervention while testing protocols to ensure the design can be scaled to a regional full-scale trial. While some stigma interventions demonstrate efficacy under highly controlled trial conditions but are not scaled, we have intentionally developed this protocol using a pragmatic design for use in community settings increasing the likelihood of adoption, sustainment, and dissemination. A team of HIV-stigma experts will guide this novel study that includes bi-directional capacity building and engages SGM living with HIV throughout the process.

Author contributions

HB, RRP, and JMT are protocol Principal Investigators. HB led the development of this manuscript with guidance from JMT. DML led statistical analysis development. RRP and NVD provided Caribbean context and related scientific guidance. SN and LN contributed senior-level specialized knowledge. JW was responsible for community engagement and civil society. CLB and ICR led study implementation. All co-authors contributed to the writing and editing of this protocol manuscript.

Funding support

Research reported in this publication was supported by the National Institute of Mental Health (NIMHD) and the Fogarty International Center (FIC) of the National Institutes of Health (NIH) under Award Numbers R21MH124083 and R21TW011761. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We thank Katelin Adams and Analía Henríquez Cross for their early work supporting this project. We also acknowledgement the contributions of our intervention facilitators, data collectors, and community advocates: Dr. Rosa Mayra Rodriguez-Lauzurique, Mr. Elias Ramos, and Ms. Nairovi Castillo. We also acknowledge the political support and encouragement of the Servicio Nacional de Salud (SNS) authorities, especially Dr. Rubelina Santos.

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