Evaluation of a Theory-Based Behavior Change Intervention to Increase HIV Self--Testing Uptake and Linkage to HIV Prevention, Care, and Treatment Among Hard-to-Reach Populations in Northern Tanzania

Njau B[1*], Damian J D[2,3], Lisasi E[3], Mushi D[1], Boulle A[3] and Mathews C[3,4]

[1]Kilimanjaro Christian Medical University College, Moshi, Kilimanjaro, Tanzania

[2]Ministry of Health, Dodoma, Tanzania

[3]School of Public Health and Family Medicine, University of Cape Town, South Africa

[4]Health Systems Research Unit, South African Medical Research Council, Cape Town, South Africa

[*]**Corresponding Author:** Njau B, Kilimanjaro Christian Medical University College P.O. Box 2240, Sokoine Drive, Kilimanjaro, Tanzania, Tel: 0784300846, E-mail: biesein2007@gmail.com

Abstract

Introduction: Tanzania aims for 95% of persons living with HIV (PLHIV) to know their serostatus by 2023.

Methods: An uncontrolled before-after study design was conducted between March 2018 (pre-intervention phase) and July 2018 (post-intervention phase). A total of 183 participants (males=89; females=94) were recruited for this study. Data were collected at baseline and at the one-month and three-month follow-ups using a pre-and post-test semi-structured questionnaire. Descriptive data are presented using measures of central tendency and their respective measures of dispersion. No comparative statistical analysis was performed.

Results: The feasibility and uptake of HIVST was 97.8% (n= 179), as all participants recorded their self-testing process correctly and tested for HIV using OraQuick HIVST kits. Of the 179 participants, 51.4 % (n=92) were women and 48.6 % (n= 87) were men. First-time testers for HIV were 11.7% (n=21), and 85.7 % (n=18/21) were men. Repeat HIV testing after HIVST at three-months follow-up was higher among males compared to females (66.7% vs. 43.5%). There was a statistically significant difference in the mean score changes for the IBM constructs pre- and post-intervention, by gender. For male participants, mean score changes were for descriptive norms, perceived control, and self-efficacy (increase of 16.6 to 18.4; 22.4 to 23.6; and 39.4 to 42.8, respectively), but not for injunctive norms (decreases of 22.1 to 19.2). For female participants, the mean score changes were for descriptive norms, perceived control and self-efficacy (increases of 16.5 to 19.2; 19. 2 to 20.0; and 38.8 to 42.8 respectively) and not for injunctive norms (decreases of 21.1 to 19.4).

Conclusions: This study highlighted high feasibility and uptake of HIVST, with the potential to identify first-time testers and promote repeat HIV testing, especially males. Descriptive norms, perceived control, and self-efficacy were supportive of the BCI to increase HIVST uptake among hard-to-reach populations in the study setting.

List of Abbreviations: ART: Antiretroviral treatment; BCI: Behavioural change intervention; CTC: Care and treatment center; DIT: Diffusion of innovation Theory; FBW: Female bar worker; HIVST: HIV self-testing; IBM: Integrated behavioural model; MMCP: Male mountain climbing porter; PCA: Principal component analysis; PE: Peer educators; PrEP: Pre- exposure prophylaxis; VCT: Voluntary Counseling and Testing; VMMC: Voluntary medical male circumcision.

Introduction

The UNAIDS has declared global targets of 95-95-95, which states that 5 % of people living with HIV are aware of their HIV status, 95% of those living with HIV are on antiretroviral treatment (ART), and 95% of those on ART achieve viral suppression by 2030 [1]. To achieve these ambitious global targets, people must know their HIV status through HIV-testing services (HTS). Evidence has shown that HTS is an essential component of HIV control programs and an entry point for HIV care, treatment, and support services [2]. Early detection, initiation of treatment and care, and introduction of risk-reduction strategies are major benefits associated with HTS [2-6]. Despite these benefits and the wider availability of HTS options and ART for HIV-infected patients, testing rates remain low in sub-Saharan Africa (SSA) [7]. The low rates of HTS uptake in SSA are inextricably linked to stigma and discrimination related to HIV-positive results [8-10]. Health system barriers contributing to limited uptake, particularly in clinical settings, include fear of visibility, lack of confidentiality of HIV-positive test results [8], and a lack of privacy and waiting time to obtain a test result [11]. Other health system barriers associated with low uptake include a lack of human or technical resources (i.e., counselors or HIV testing reagents), long queues at HIV testing points, and inconvenient hours of operation [12-14]. Furthermore, there are gender differences in HIV testing uptake in SSA, with more women than men aware of their HIV status. Evidence shows that the uptake of HIV testing ranges between 1% and 42 % among women, while for men, it ranges between 2 % and 38% [7]. A similar scenario of sex differences in HIV testing rates has been reported in Tanzania. According to the 2016-2017 Tanzania HIV Impact Survey (THIS), only 45 % of men and 55 % of women were aware of their HIV status. Of significance, among men living with HIV who have been tested for HIV, 86% reported initiation of ART, of whom 84% reported viral suppression [15]. Several barriers explain men's reluctance to test for HIV, the key of which is their masculinity ideals, which prevent them from expressing emotions in public [16-21]. Moreover, HIV testing is a woman's domain [22, 23], perceived sense of risk related to extramarital affairs, and the resultant fear of receiving a positive diagnosis and limited time to visit HIV testing points exacerbates men's reluctance to undergo testing for HIV [8, 11, 16, 22-24]. Among women, fear of potential conflicts that may arise following a positive HIV test, particularly in unstable relationships marked by distrust, may be a barrier to HIV testing [16]. Other barriers to poor uptake of HIV testing among women include the low perceived risk of being infected with HIV because they trust their male partners, fear of visibility while visiting a testing center, which is related to sexual promiscuity and assumed HIV-positive status, and abstaining from sex or lacking a sexual partner [11]. Such barriers limit progress towards the UNAIDS 95-95-95 global targets by 2030 and call for universal scaling up of HTS [2]. Complementing existing HTS approaches with novel testing methods, such as HIVST, may overcome or circumvent some of the barriers to HIV testing. [25] Studies from Kenya [26, 27], Malawi [28], Nigeria [29], Uganda [30], Tanzania [31, 32], DRC [33] and South Africa [34-36], have demonstrated high acceptability and uptake of HIVST in SSA [37]. These studies have also shown that HIVST interventions may be effective in increasing the uptake of HIV testing in the general population, among young people, and in key populations [38-42]. In 2012, the US Food and Drug Administration approved oral HIVST [43], and in 2015, oral HIVST was authorized in Europe [44]. In low-income countries, including African countries, regulated HIVST kits are not yet available for the general population [45]. In December 2016, the World Health Organization (WHO) formally recommended HIVST as an additional option for HTS [25] and to develop and validate HIVST [46,

47]. Despite the existing WHO HIVST guidelines and technical recommendations that highlight the potential contribution of HIVST to close gaps in universal HIV testing coverage, most SSA countries, including Tanzania, have lagged in the adoption of HIVST [46, 47]. HIV policymakers, experts, and government stakeholders in many African countries have expressed several concerns, challenges, and criticism related to HIVST [36, 48]. The main concerns against HIVST include potential psychological and social harm due to lack of face-to-face counseling, risks of inaccurate results, and uncertainty over linkage to care for individuals with a reactive HIVST test result [36, 48-50]. Since HIVST is a new modality, some of the concerns about HIVST, such as the potential for psychological and social harm, are not found in evidence [50]. In Tanzania, HIVST is recognized as a potential testing option to increase HIV testing rates in high-risk populations [51]. In addition, the National AIDS Control Programme (NACP) is preparing HIVST guidelines to assist potential users in accessing HIV care treatment and support, including confirmatory tests, initiation of ART, and PrEP [23]. As of July 2018, Tanzania's National HIV Testing Guidelines did not allow for HIVST. However, at the time of writing, plans were underway to change the law to allow the use of HIVST. Further changes are expected in the introduction of HIVST into the national HTS policy, which will be informed by findings from ongoing studies among key populations in selected regions with high HIV prevalence in the country [51]. At the time of the study, there was no evidence of using theory-based behaviour change interventions (BCI) to increase HIVST uptake and linkage to HIV prevention, care and treatment among hard-to-reach populations in Northern Tanzania. Behaviour change interventions based on theory are recommended to explain behaviour change determinants. This study examined the effects of descriptive norms, perceived control, and self-efficacy on change in Female bar workers (FBWs), and Male mountain male porters (MMCPs). The aim was to fill in the knowledge gap and determine the causal link between BCI constructs and an increase in HIVST uptake and linkage to HIV prevention, care, and treatment. The results of this study will inform HIVST interventionists and HIV policymakers about the most effective BCI constructs to promote HIVST uptake. In addition, it will enhance the linkage to HIV prevention, care and treatment among hard-to-reach populations in the study settings.

Methods

Study Setting and Population

The study was conducted in an urban setting in Northern Tanzania with a high HIV prevalence and low uptake of HTS. The Kilimanjaro Region has a total population of 1.6 million and an average household size of 4.3 [52]. The study area is located in a tourist circuit, with major national parks and the highest mountain in Africa, Mt. Kilimanjaro. Most tourist hotels and bars are located in Northern Tanzania. An HIV prevalence report of eight regions in the country, including two in Northern Tanzania (Kilimanjaro and Arusha), witnessed an increase in prevalence despite the overall decline in national HIV prevalence. For example, HIV prevalence increased from 1.9% in 2007/08 to 3.8 % in 2011/12 in the Kilimanjaro region. The Moshi Municipal Council is of the seven (7) districts in the Kilimanjaro region of Tanzania. The other six districts are Rombo, Mwanga, Same, Moshi Rural, Hai and Siha District Councils. The Moshi Municipal Council has an estimated population of 184,292 in 21 wards (i.e., administrative units) with an average household size of 4.0 [52]. At the time of data collection, 18 facilities were providing HTS. In addition, 21 HIV care and treatment centers (CTC) provide access to antiretroviral therapy (ART), in the study setting [53]. The study population comprised Female bar workers (FBWs) and Male mountain climbing porters (MMCPs) from the Kilimanjaro region. It is estimated that 2,000 young women between the ages of 18 and 40 work in more than 600 licensed establishments, with additional FBWs working in unlicensed alcohol-selling venues in the study setting. In the study setting, HIV prevalence among FBWs was proportionally higher (19% to 26%) than that in the general population (5.1%) [15]. The observed high HIV prevalence among FBWs is associated with HIV-risk behaviors such as excessive alcohol consumption, multiple sexual partnerships, and transactional sexual practices [54, 55]. Although 95 % of FBWs reported ever tested for HIV, 41% of those who have tested have never repeated HIV testing in the past year [56]. An estimated 17,000 porters working in the tourist industry are predominantly young men (aged between 18 and 45 years), who are very mobile and face volatile income cycles [57]. According to Lyamuya et al. (2017), the behavior of MMCPs puts them at risk of HIV infection. These behaviors include unprotected sex, multiple concurrent sexual partnerships, substance use, alcohol consumption, and marijuana use [58]. Additionally, one-third of MMCPs have never been tested for HIV

despite engaging in high-risk behaviors for HIV infection [56].

Study Design

An uncontrolled before-after study design was conducted between March 2018 (pre-intervention phase) and July 2018 (post-intervention phase). The before-after study design used a "historical" comparison in the form of the "control group." This study aimed to compare changes in values within individuals over time, before the intervention (pre-test), and after the intervention (post-test), and not between the individual and a comparison group. The same individuals were tested before and after the BCI. Because of the nature of the before-and-after design, no baseline data on the outcomes of interest were collected. In addition, the study used a 'one-time point' measurement after the intervention. The desired level of confidence interval (CI) at 95%, a significance margin error (ME) of 5%, and 87.2 % proportion of HIVST uptake were included in the formula as follows:

$$N = \frac{Z^2 x P x (100 - P)}{\in^2}$$

Where: N = Estimated sample size, Z = Standard Normal deviation of 1.962 corresponding to 95% CI, P=Proportion of the primary outcome under study, and E= Marginal Error at 5% [59]. The final sample size was derived using the following formula:

$$Final sample size = \frac{Effective sample size}{(1 - Anticipated non - response rate)}$$

The minimum sample size was estimated to be 170, and the anticipated non-response or dropout rate was 10 %, derived from a previous study conducted in the same setting. The final sample size was 170/(1-0.1)= 188 [60]. The baseline data was collected from all eligible participants who agreed to participate in the study before the BCI was offered to those who agreed to participate in the intervention. Participants who participated in the intervention were followed up for 12 weeks (three-months) to measure the outcomes of interest.
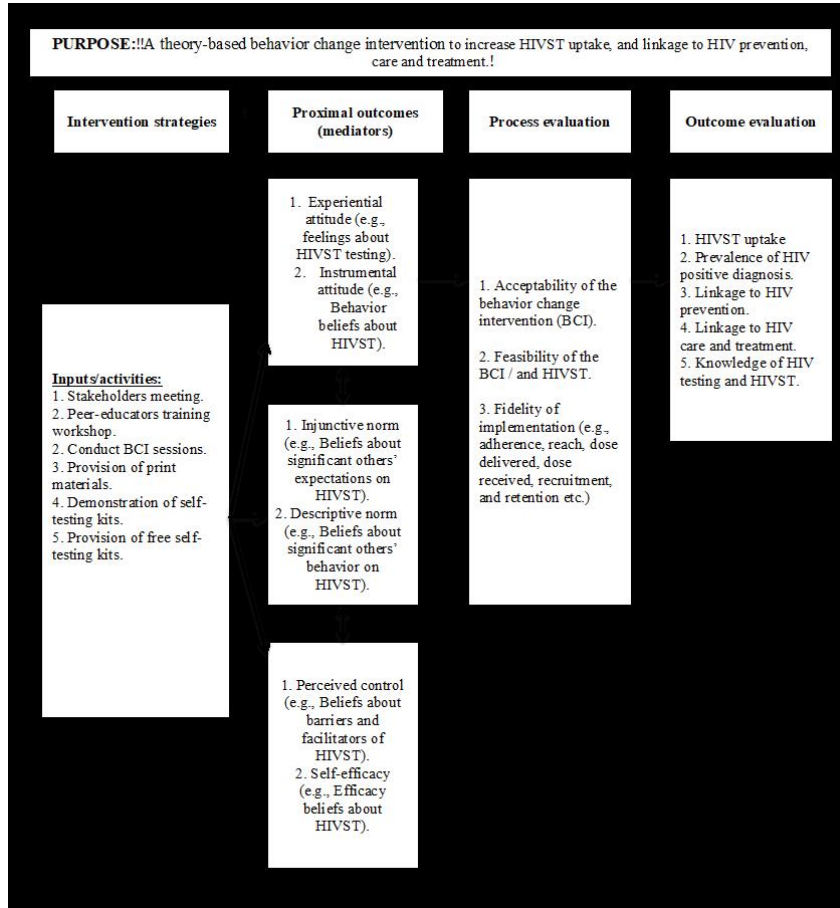
Logic Model for Implementation

A logic model (Figure 1) was developed to make explicit the theoretically informed assumptions about the determinants of behavioral change and how intervention strategies are assumed to affect them. The logic model demonstrates the intended pathways of behavior change from the intervention strategies through change mechanisms (mediators) and the intended process and impact outcomes guided by the integrated behavior model of behavior change.

Study Participants

Participants who were 18 years of age or older at the time of enrolment and who self-reported an HIV-negative status and had not had an HIV test in the past three months or self-reported that their HIV status was unknown were recruited. The recruitment strategy involved invitations delivered by trained peer educators (PEs) to eligible participants to visit the study office within the study setting for consenting to participate in the study. All eligible participants provided written informed consent to participate in this study. Participants who provided written consent were sent back to the trained PEs to schedule attendance during the first intervention session. Ethical approval was obtained from the Kilimanjaro Christian Medical University College Ethics Committee (CREC: 884; dated6/1/2016) and the National Institute of Medical Research in Tanzania (NIMRlHQIR.8a/Vol. IX/2454; dated: 18/4/2017), and the Health Sciences Research Ethics Committee at the University of Cape Town in South Africa (HREC REF:737; dated:9/11/2016). The Tanzania Food and Drug Authority (TFDA) approved Oral HIV kits. Written informed consent was obtained from all eligible participants. The participants were aware of their voluntary participation and freedom to withdraw at any

point in the research.

Figure 1: Logic model for the implementation of the IBM behaviour change intervention (Source: Logic model constructed by the author).

Presents a description of the logic model for the implementation of the BCI including the intervention strategies (inputs/resources), proximal outcomes (IBM constructs), process outcomes (acceptability, feasibility, and fidelity of implementation), and impact outcomes (HIVST uptake, prevalence of HIV-positive diagnosis, linkage to HIV prevention, care and treatment, and knowledge of HIV testing and HIVST).

Outcomes

Demographics

The following demographic information was collected at baseline from eligible study participants using a semi-structured paper-based questionnaire: sex, age, marital status, level of education, religion, and living arrangement.

Knowledge of HIV Testing and HIVST

Knowledge of HIV testing and HIVST was assessed by asking all participants at baseline about whether they knew a place to test for HIV, previous HIV testing history, experiences of using HIVST and whether they knew someone who had ever used HIVST.

Feasibility of HIVST

Feasibility refers to the extent to which HIVST are utilized within the study setting. Study staff members assessed the feasibility of HIVST within 24 to 72 hours of post-testing by reviewing the documentation of the self-testing process. The study staff recorded the kits used or unused by the participants. They also recorded the participants' self-test results, as recorded in the interpretation of the results form, and compared them with the results displayed in the self-test kit. All discrepancies in the interpretation of the self-test results were discussed between the first author [BN] and the participant and corrected accordingly. In the case of invalid

self-test results, the first author [BN] offered another self-test kit to the participants to test under supervision.

HIVST Uptake

Participants were asked if they had been tested for HIV using HIVST during the three months follow-up period to assess HIVST uptake. HIVST uptake was rated using a binary YES/NO response format.

Prevalence of New HIV-Positive Diagnosis

The prevalence of a new HIV-positive diagnosis was the proportion of participants who offered HIV testing that was diagnosed as HIV-positive. We assessed the number of new HIV–positives by asking all participants who had accepted HIVST to categorize their test results at a three-month follow-up. The outcome options were coded as follows: 0=test not working, 1=may have HIV, and 2=does not have HIV.

Linkage to HIV Prevention

Linkage to HIV prevention was the proportion of individuals with negative test results who sought HIV prevention services (e.g., voluntary medical male circumcision, condoms, contraception) within three months of being offered HIVST kits out of all HIV–negative participants.

Linkage to HIV Care and Treatment

Linkage to HIV care and treatment was the proportion of individuals with positive test results who underwent a confirmatory HIV test within three - months of being offered HIVST kits and who were initiated for ART. Linkage to HIV care and treatment was assessed by asking participants who reported HIV-positive results whether they had sought medical care for confirmatory HIV tests and initiated ART and reviewed HIV care and treatment clinic records.

Integrated Behavioral Model Constructs

The before and after changes in the IBM constructs were assessed at the one-month and three-months follow-ups using a pre-and post-test semi-structured questionnaire. Participants rated their perceived norms, perceived control, and self-efficacy regarding HIV.

Procedures

Baseline Survey

A semi-structured paper-based questionnaire for each of the surveys (baseline and three months post-baseline) was distributed to eligible participants between January and March 2018 and June and July 2018. The Swahili-based questionnaires incorporated four belief-based IBM constructs (i.e., injunctive norm, descriptive norm, perceived control, and self-efficacy) because they are most conducive to change [62]. The eligibility criteria for participation were that participants must be over 18 years of age, have not been tested for HIV in the past three months before the date of recruitment, or be unaware of their HIV status. Four (males=2; female=2) trained research assistants (RAs) with previous experience in HTS studies explained the purpose and objectives of the study, and if participants were eligible and willing, the RAs provided informed consent. The RAs conducted the surveys, and the completion of the questionnaires took an average of 45 minutes. The surveys were conducted in a quiet place in the study offices to ensure privacy and confidentiality. A pilot test was conducted before the baseline survey to assess the validity of the questionnaire. The questionnaire was piloted to a convenience sample of 10 (males = 5; females=5) clients attending a stand-alone VCT center within the study setting for clarity of language, questions, internal consistency, and competency of the four trained RAs. Minor adjustments (i.e., wording, sequence of questions, and coding) were performed accordingly.

The IBM Behaviour Change Intervention

The IBM behavior change intervention, *Jitambue* (the Swahili word for Know your Self), was a multi-component intervention based on the Integrated Behavior Model (IBM) [63, 64] and Diffusion of Innovation Theory (DIT) [65] for the implementation of health-related services [66-68]. Findings from systematic reviews and the formative study with key informants, FBWs, and MM-CPs also informed the development of the IBM behavior change intervention [69-71]. The development of the manual IBM behavior change intervention has been described elsewhere [72]. OraQuick is fully WHO pre-qualified and uses oral fluid swabs from the upper and lower gums that are placed into a pre-filled tube of reagent for 20 min. When used by laypersons in Kenya, the self-test had a sensitivity of 89.7% and a specificity of 98.0% [27]. The self-test kits with all necessary components packaged in a pocket-size plastic pouch were procured through a local agent and distributed to participants free of charge. As HIVST is not available in Tanzania, participants viewed a professionally developed video to introduce the concept of HIVST. The video helped standardize the information provided to participants and limit interviewer-specific discrepancies in the content and quality of the instructions provided. In brief, the video featured an adult African man demonstrating how to use an oral-based HIV test (OraQuick Advance HIV-I/2; OraSure Technologies, Bethlehem, PA), with all instructions in Swahili, a local language familiar to the participants.

Participants were allowed to view the video twice and were allowed to ask any questions for clarification. They were subsequently asked to repeat the demonstration by simulation using a dummy oral HIVST kit. In addition, the participants received an instruction sheet with pictorials in Swahili and English, adapted from a previous HIVST study in Kenya (S1 Fig). The user instructions contain images of how to interpret the test window for negative, positive, and invalid results [27].

Since HIVST can only be used for research purposes in Tanzania, the first author [BN] distributed the HIVST kits to all participants who agreed to test for HIV at the end of session two. According to the manufacturer's recommendations for repeat HIV testing, participants were informed to repeat HIV testing three months after receiving a negative test result. Participants reporting a preliminary HIV-positive result were informed that they would immediately seek a confirmatory HIV test.

All participants received a large brown envelope to carry their HIVST kits and were asked to return the used or unused kits in person within one–three days (24-72 hours) at the study office. All participants who received the HIVST kits were provided with a mobile phone number to call if they needed help using the HIV self-test kits or with any other assistance related to the study. A participant who reported a preliminary HIV-positive result received a referral letter to seek confirmatory HIV testing and initiation of ART at any HIV care and treatment center of their choice within the study setting. All kits were discarded according to the manufacturer's instructions under the supervision of the first author. Follow-up survey In the three-month survey, participants were asked to visit study offices located within the Moshi Municipality. The RAs contacted participants by phone (consent was obtained to make phone calls to all participants) to make appointments.

Data Analysis

Descriptive Analysis

Data was entered, cleaned, recoded, and analysed using Statistical Package for Social Sciences (SPSS) version 27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). Mean (± standard deviation) were used to summarize numerical variables conforming to normal distribution, median (Q25-Q75) for non-normal distribution, and frequency (percentage) was used to summarize categorical variables.
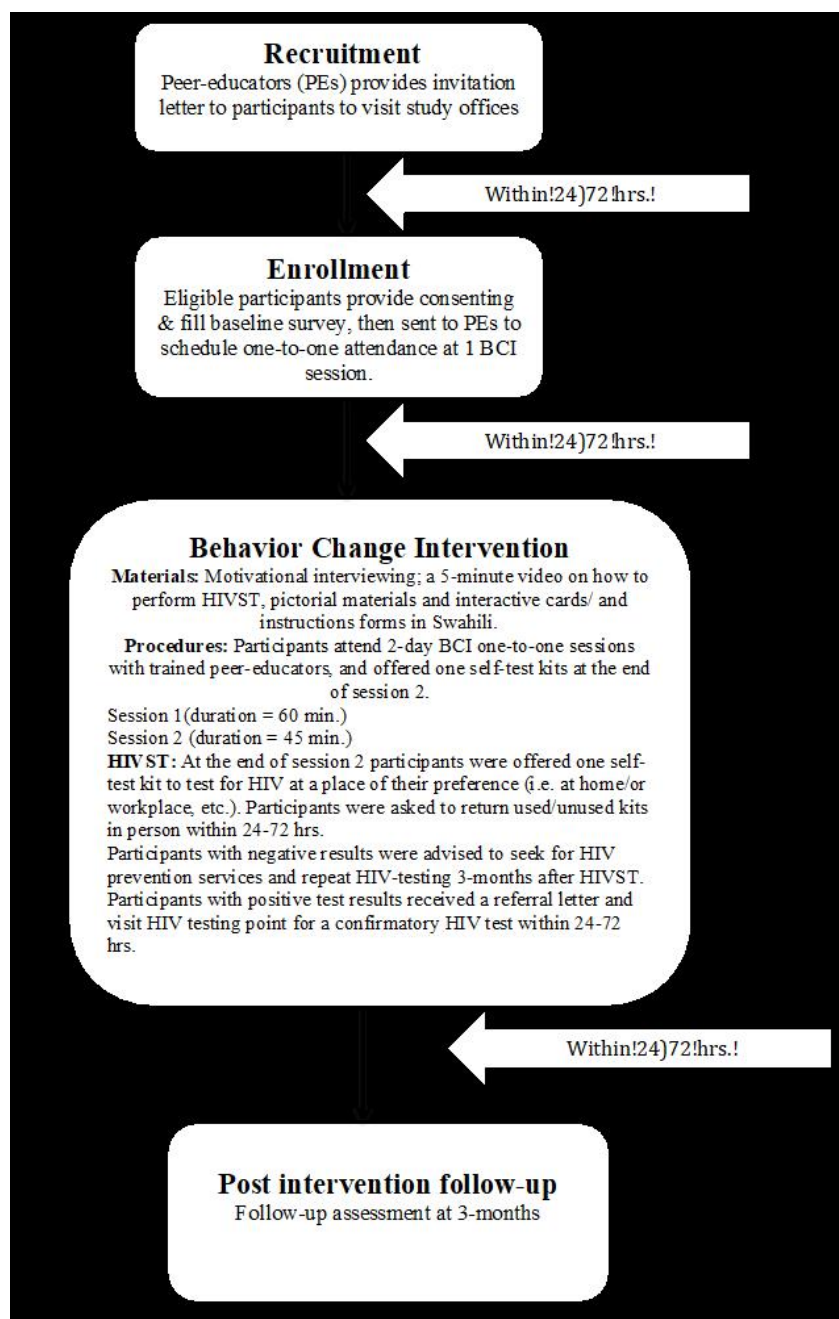
Figure 2: The process and timelines of the before after study design.

Presents the process and timelines of the before and after study design including recruitment to post intervention follow-up.

If the RAs failed to contact a participant in three consecutive calls, they were declared lost to follow–up. The RAs recorded all changes in HIV-testing intentions, plans, and actual testing during the intervention. Reasons for refusal were carefully documented, along with HIVST experiences and unsuccessful follow-up. Figure 2 shows the process and timelines of the before-after study design.

Bivariate Analysis

An internal reliability test was performed for the items assessing IBM constructs with a cut-off point of Cronbach's alpha coefficient value of 0.6 or higher as satisfactory [73]. A paired sample t-test was used to calculate mean scores per IBM constructs to assess whether the pre-test and post-test mean differences were statistically different from each other. During the analysis, a reversed Likert scale was used to score the responses with 1 point = neutral and 5 points = strongly agree. Eight (8) items assessed the per-

ceived norms (injunctive) construct, with a total score ranging from 8 to 40. A higher score is considered supportive of the BCI. The reliability scale was Cronbach's alpha = .61.

Four (4) items assessed the perceived norms (descriptive) construct, with total scores ranging from 4 to 20. A higher score was considered supportive of the BCI. The alpha coefficient value = .72. Seven (7) items assessed the personal agency (perceived control) construct, with a total score ranging from 7 to 35. A higher score was considered supportive of the BCI. The alpha coefficient value = .71.

Ten (10) items assessed the personal agency (self-efficacy) construct, with a total score ranging from 10 to 50. A higher score on the personal agency (self-efficacy) construct was considered supportive of the BCI. The alpha coefficient value = .81. See Table S1.

Principal Component Analysis

Principal component analysis (PCA) was performed to identify the sub-groups of IBM items forming subscales. Before performing PCA, we assessed the suitability of the data. The correlation coefficient was set at a cutoff point of .3 or above. Kaiser-Meyer-Oklin value was used to assess sampling adequacy at a cut-off point of 0.6 [74, 75], while Bartlett's, [76] test of sphericity supported the factorability of the correlation matrix. Additionally, Carell's scree test [77] and Eingen value of over 1.0 was set for the amount of the total variance explained by a factor. Furthermore, the varimax method was used to minimize the number of variables with high loadings on each factor. The 32 items of the IBM constructs were subjected to exploratory PCA. Before conducting PCA, the suitability of the data for factor analysis was assessed. Inspection of the correlation matrix for IBM constructs revealed the presence of many coefficients of .3 and above. The Kaiser-Meyer-Oklin value was .744, exceeding the cut–off point of .6, and Bartlett's Test of Sphericity was statistically significant (p< 0.001). Given the sufficiency of the sample and Kaiser's criteria, all 32 items were retained in the final analysis. Using Catell's scree test, nine components above the breaking point on the scree plots of the IBM constructs were retained for further analysis.

Further analysis using Varimox method revealed strong loading of the 9 components with eigenvalues exceeding 1, explaining 3.02 %, 2.91 % 2.77 %, 2.40 %, 2.15 %, 2.02 %, 1.98 %, 1.63 %, and 1.48 % These nine components accounted for 73.3 % of the variance. The nine items included injunctive norms (two items), descriptive norms (two items), and self-efficacy (five items). The internal reliability of the items was indicated by Cronbach's alpha coefficients of 0.767. Table S 2 shows the factor loadings after rotation.

Results

Recruitment Rate and Retention

Two hundred and twenty-four (n=224) participants (n=110 MMCPs; n=114 FBWs) were sampled and invited to participate; 183 (n= 89 MMCPs; n= 94 FBWs) consented and were enrolled in the study. This was a recruitment rate of 82.1%. Those who did not meet the inclusion criteria comprised 21 MMCPs and 20 FBWs. Three (3) participants declined to participate in BCI after completing the baseline survey. The reasons mentioned for refusal to participate were lack of time, perceived inaccuracy of the HIVST test, and fear of positive HIV test results. Of the 89 MMCPs, only 1 refused to participate. The remaining 88 MMCPs attended both sessions. Of the 94 FBWs, only 2 refused to participate. The proportion of enrolled participants who completed the assessment at the three months follow-up, with a 60% retention rate, was considered the benchmark for retention. Overall, the retention at three months follow-up was 99.5% (MMCPs = 99%; FBWs = 100%). See Figure 3
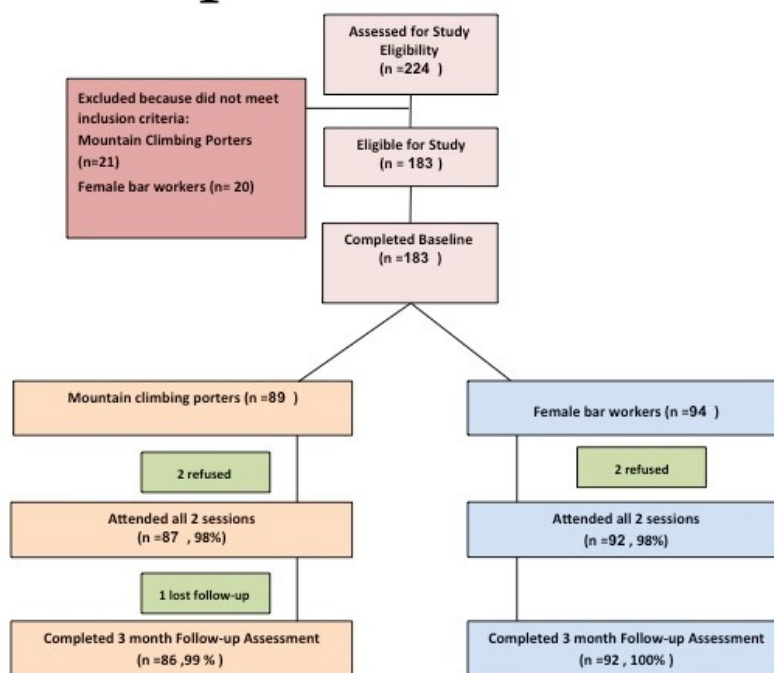
Figure 3: Participant's flow chart (Source: designed by the 1st author)

Presents participant's flow chart from recruitment to completed 3 months follow-up assessment by gender.

Knowledge of HIV Testing and HIVST

The overall knowledge of HIV testing of participants was high, with 98.9 % of women knew where to test for HIV. The history of those who had been previously tested for HIV differed significantly between women and men (p< 0.001). More women than men (96.8% vs. 79.8%) were tested for HIV during their lifetime. Nearly, two-thirds (65. 2 %), of men reported HIV testing in the past 3 months. As expected, very low proportions of both female (8.5%) and male (3.4%) participants had ever used HIVST. Finally, 38.3 % of female participants knew someone who had self-tested for HIV (see Table 1).

Table 1: Baseline characteristics, knowledge of HIV testing and HIVST of respondents (n=183).

Variables	Females	Males	*P*-value
	N=**94 (51.4%)**	N=**89 (48.6%)**	
Age of participants (Mean ± SD, years)	31±7.8	33±7.1	0.146
Never married	49 (52.1)	30 (33.7)	<0.001
Had primary education	40 (42.6)	42 (47.2)	0.443
Christian	71 (75.5)	58 (65.2)	0.124
Live with husband/wife	18 (19.1)	37 (41.6)	0.001
Living alone	55(58.5)	38(42.7)	0.001
Knowledge of HIV testing and HIVST			
Knows the place to get tested for HIV	93(98.9)	81(91)	0.013
Ever been tested for HIV	91 (96.8)	71 (79.8)	0.001
Recent HIV testing			
Within the past 3 months	54(57.6)	58(65.2)	0.077
Within the past 1 year	40(42.4)	31(34.8%)	0.081

Ever used HIVST before (Yes)	8 (8.5)	3 (3.4)	0.144
Knows someone who has ever self-tested	36(38.3)	26(29.2)	0.194
Use of Family planning (for women only)	55(58.5)	N/A	N/A
Male circumcision (for men only)	N/A	89(100%)	N/A

Baseline Characteristics of Respondents

Table 1 shows the baseline characteristics of the study participants. At baseline, 183 participants (MMCPs =89; FBWs = 94) participated in this study, with a response rate of 97.3%. The mean age of the women was 31 years [SD = 7.8]. The mean age of the men was 33 years [SD = 7.1]. Of the 183 participants, half (51.4%, n= 94) were females. Almost half of the women (n=40/94; 42.6%) had primary education, 75.5 % of women were Christians, 52.1% of women (n=49/94) were single, and 58.5 % of women were living alone (Table 1).

Feasibility of HIVST

The feasibility of HIVST was assessed within 24–72 hours post-testing. The majority of participants (98.9%; n= 179) of both the FBWs and MMCPs recorded their self-testing process correctly. All results were confirmed upon inspection of the test kits and documentation of the interpretation of the results. Two participants (1= male; 1= female) reported invalid results. The reason for the invalid test results was that the participants did not collect oral fluid before immersing the collection device in the reagent. Repeated tests were performed under supervision, and the results were negative. Apart from the two participants who reported invalid test results, the remaining participants self-tested without supervision.

HIVST Uptake

Of the 183 participants recruited in the study, the majority (97.8%, n=179) participated in the BCI and tested for HIV using the OraQuick HIVST kits. Of the 179 participants, 51.4 % (n=92) were women, and 21 (11.7 %) had never previously been tested for HIV. Of the 21 first-time testers, 18 (85.7%) were men. The majority (91.3 %) of women reported self-testing the same day they received the self-test kits. Two (1.1 %) participants (1 male and female respectively) reported reactive test results. The majority (98.9 %) of participants reported HIV-negative test results when returning the test kits within three days (24 to 72 hours) of receiving the kits. At the three-months follow-up, the two participants with a positive HIVST test result reported that they had visited a health facility for confirmatory HIV testing and ART initiation within 2 weeks post-self-testing. Furthermore, at the three-months follow-up, nearly, one-third (29.3 %, n= 27/94) of women who reported not using any type of family planning (FP) at baseline reported that they had visited family planning clinics. Two-thirds (66.7%) of men who received negative results reported repeat HIV testing (using conventional HTS) three months post-HIVST (Table 2).

Table 2: HIVST uptake (N= 179).

	Females	Males	*P*-value
Variable	N=**94 (51.4%)**	N=**89 (48.6%)**	
Participated in HIVST intervention: (n=183)			
Yes	92(97.9)	87(97.8)	0.956
No	2(2.1)	2(2.2)	
The time before performing HIVST: (n=179)			
Same day	84(91.3)	69(79.3)	0.059
24 hours	5(5.4)	16(18.4)	

More than 24 hours	3(3.3)	2(2.3)	
HIVST results: (n= 179)			
Reactive	1(1.1)	1(1.1)	0.818
Negative	91(98.9)	86(98.9)	
Interpretation of results: (n=179)			
Correct interpretation	91(98.9)	86(98.9)	0.391
Incorrect interpretation	1(1.1)	1(1.1)	
Type of HIVST: (n=179)			
Supervised	1(1.1)	1(1.1)	0.503
Unsupervised	91(98.9)	86(98.9)	
Action taken after HIVST (n= 179)			
Went for confirmatory test/started ART	1(1.1)	1(1.1)	0.771
Started family planning	27(29.3)	0(0.0)	
Repeat HIV testing after 3 months of HIVST	40(43.5)	58(66.7)	
Done nothing after HIVST	24(26.1)	28(32.2)	

Presents selected factors associated with HIVST uptake by gender among 179 participants. The findings are presented as proportions and P--value. Totals are by column.

Comparison of IBM Constructs Before and After the Intervention

Table 3 describes the IBM construct scores before and after BCI for perceived norms (injunctive and descriptive norms), perceived control, and self-efficacy. IBM constructs before and after BCI by gender. Pre- and post-test scores differed significantly for all measures ($p < 0.001$). For both male and female participants, there was a significant increase in three of the four IBM construct scores supportive of the BCI. For male participants, significant mean score increase was observed in descriptive norms, perceived control, and self-efficacy i.e., 16.6 to 18.4; 22.4 to 23.6; and 39.4 to 42.8, respectively), but not for injunctive norms (decreases of 22.1 to 19.2). For female participants, similar pattern was observed i.e., descriptive norms, perceived control and self-efficacy (16.5 to 19.2; 19. 2 to 20.0; and 38.8 to 42.8 respectively) and not for injunctive norms (decreases of 21.1 to 19.4).

Table 3: IBM constructs scores before and after intervention by gender (n=179)

IBM constructs	Male			Female		
	Baseline(Mean ± SD)	Follow-up(Mean ± SD)	P-value	Baseline(Mean ± SD)	Follow-up(Mean ± SD)	P-value
Injunctive norms score	22.1± 3.0	19.2± 1.6	<. 0001	21.1 ± 3.4	19.4 ± 2.3	<. 0001
Descriptive norms score	16.6± 3.1	18.4±2.8	<. 0001	16.5 ± 2.3	19.2 ± 2.4	<. 0001
Perceived control score	22.4 ±5.7	23.6 ±5.4	<. 0001	19.2 ± 4.5	20.0 ± 5.1	.02
Self-efficacy score	39. 4 ± 3.8	42.8 ±3.1	<. 0001	38.8 ± 5.1	42.8 ± 5.4	<. 0001

Presents IBM constructs score for injunctive norms, descriptive norms, and self-efficacy by gender at baseline and follow-up among 179 participants. The scores are presented as mean, standard deviation and P-value.

Discussion

This study used a before-after study design aimed at assessing the impact of a theory-based BCI to increase HIVST uptake and linkage to HIV prevention, care, and treatment among FBWs and MMCPs in Northern Tanzania.

Knowledge of HIV Testing and HIVST

At baseline, the participants demonstrated high HIV and AIDS awareness and knowledge, including HIV testing. Most participants were aware of HIV and AIDS, routes of HIV transmission, and the efficacy of condoms in HIV prevention and antiretroviral therapy (ART). Furthermore, most participants knew places in their vicinity where they could test for HIV. This observation is in line with studies conducted in other settings in Tanzania that demonstrated a high level of HIV and AIDS awareness and knowledge [15, 78]. However, this observation is contrary to a study among adolescents in rural Mozambique, which observed limited knowledge of HIV transmission [79]. In contrast, most participants in this study were unaware of HIVST before the survey. This is not a surprising finding because HIVST is regarded as a 'new' technology for HTS and corroborates similar results from SSA [22, 23, 33, 34, 79].

Feasibility of HIVST

The feasibility of HIVST was high, with the majority of participants correctly documenting their self-testing processes. Additionally, two invalid test results were documented in this study. This observation is in line with findings from other settings, where invalid test results are a common problem of HIVST with the variability of rates between settings and populations [79-81]. In the current study, the reason for the invalid test results was related to errors in sample collection, which has been documented in other studies as a reason for invalid HIVST results [80, 82]. This observation suggests the need for adequate supportive materials and resources accompanying the distribution of self-test kits, which will improve participants' skills and confidence in the use of the kits [83].

HIVST Uptake

The study findings demonstrated a high HIVST uptake among the targeted populations in this setting. This finding concurs with studies on HIVST uptake in different settings [37, 84-87]. This observation could be explained by the fact that the participants were offered HIV using OraQuick HIVST kits. Existing evidence from other studies from SSA suggests that the majority of participants preferred oral HIVST compared to blood-based tests because it is easy to use and less invasive due to the absence of a finger prick [88-90]. The HIV-positive results reported by participants from the HIVST were low and do not support the idea that MMCPs and FBWs are at particularly high risk for HIV infection. An explanation could be that all eligible participants who knew they were HIV-positive were excluded from this study. The rationale for excluding known HIV-positive participants was to avoid overestimation of new HIV-positive diagnoses [91, 92]. An alternative explanation could be that MMCPs and FBWs who are at higher risk are even harder to reach. Our study was able to reach people who had never been tested for HIV before and concurs with findings, which reported that HIVST could identify and reach first-time testers because it provides an opportunity for individuals to test for HIV. The first-time testers in this study were excited to test for HIV for the first time in their lifetime through HIVST. These findings indicate the potential of HIVST to reach first-time testers and may be beneficial for hard-to-reach populations who have never been tested for HIV before [37, 42, 93]. All participants in the current study found that the oral HIVST kits were very easy to use, in the privacy of their place of preference and convenient time. This observation concurs with findings reported from HIVST studies conducted in other settings [88-90]. In this study, the few participants who refused to participate in the intervention mentioned perceived inaccuracy of the oral HIVST kits, fear of a positive test result and inability to perform HIVST alone as

reasons for refusal to participate. Similar concerns have been reported from HIVST studies and underline the importance of addressing such impediments for HIVST uptake [20, 89, 96-98].

Linkage to HIV Prevention, Care and Treatment

Participants who reported a negative HIV self-test were offered information about HIV prevention services, including Voluntary Medical Male Circumcision (VMMC), and family planning. Voluntary Medical Male Circumcision (VMMC) was self-reported by all male participants at baseline survey. This was not a surprising finding because of an ongoing campaign in Tanzania to promote VMMC since 2010 [94]. Almost one-third of female participants who did not use any type of family planning at baseline visited a family planning clinic post-intervention. The provision of preventive materials and support by peer educators may have facilitated women family planning-seeking behaviour in this study setting.

In this study, a link between care and ART initiation following a positive HIVST result was reported. At the three-months follow-up, two participants who received HIV-positive results reported visiting a health facility for confirmatory HIV testing and initiated ART within 2 weeks post-HIV self-testing. This result should be interpreted with caution because the current study lacks baseline data on the linkage between HIV care and treatment for comparison among the target population in the study setting. Our study findings reported that more than half of the participants went to a health facility for a repeat HIV test 3 months after receiving a negative HIV self-test. This is in line with Tanzania's national HIV testing algorithm [95], and the finding suggests that an HIVST intervention such as the current study may encourage repeat HIV testing among hard-to-reach populations, such as FBWs and MMCPs.

Before and After Changes of the IBM Constructs

The study findings indicated increased scores of descriptive norms, perceived control and self-efficacy for female and male participants, with a statistically significant difference between pre-test and post-test. This coincides with other multiple intervention clinics and community-based studies and meta-analyses, showing self-efficacy is an important construct that affects the likelihood of performing the intended behaviour [62, 63, 99-101]. This observation suggests the importance of a sense of confidence over-social-psychological barriers to use HIVST. In the HIV testing context, self-efficacy might have a significant influence on the way the target population confronts HIV/AIDS-related stressors. According to IBM, both injunctive and descriptive norms are important constructs of social influence in social identity and might influence the uptake of recommended behaviour such as HIVST [62, 63, 99, 100]. However, in this study, the injunctive norms scores decreased for both male and female participants post-test, suggesting that the intervention failed to change the injunctive norms compared to the remaining four IBM constructs. According to Baranowski (2002), the injunctive norm is an individual's belief about the extent to which other people who are important to them think they should or should not perform a particular behaviour [63]. However, given the nature of HIVST, which provides autonomy and perceived self-control of the individual's ownership of testing for HIV, participants might find injunctive norms as less significant in their decision-making process. An alternative explanation for this observation could be due to methodological limitations during the design of the intervention. In addition, maybe the key normative beliefs included in the intervention were insufficient to bring about the anticipated change. From a theoretical perspective, Fishbein and Cappella [102], argue that not all beliefs are equally susceptible to direct change and may also vary across population subgroups, which could be an alternative explanation. Future BCI using the IBM constructs should consider how best to change injunctive norms.

Limitations

Several limitations need to be considered when interpreting the findings of this study. First, we used a before-after study design instead of a clinical trial to evaluate the impact of the BCI. Potential limitations of this study design include lack of a comparison or control group, inability to establish a causal-effect relationship between exposure and the outcome, inability to account temporal changes independent of the intervention and regression to mean. Despite these potential limitations, the study design was found

feasible for the evaluation of the intervention due to low cost, convenience and simplicity compared to an RCT. Second, the findings of this study may have limited generalizability to the general population of young people in Tanzania. Third, the results are based on participants' self-reports. In responding to sensitive topics such as HIV testing, participants may have over-reported or under-reported their HIV testing behaviours. This may introduce social desirability bias, which is very common with self-reporting. Another limitation is that participants' report of the use of the HIVST kits may be subject to social desirability bias. For example, participants may want to report that they used the HIVST kit when they did not. To reduce this bias, participants were asked to return the HIVST kits, either used or unused, within three days (24 to 72 hours) after receiving the kits, in order to ascertain the actual use of the HIVST kits. Moreover, this study was limited to using oral-fluid based self-tests kits. Further studies are warranted to also understand preferences for whole blood-based self-tests in this population and setting.

Conclusions

This study highlighted high feasibility and HIVST uptake, with the potential to identify first-time testers and promote repeat HIV testing, especially males. Descriptive norms, perceived control, and self-efficacy were supportive of the BCI to increase HIVST uptake among hard-to-reach populations in the study setting.

Acknowledgements

References

1. UNAIDS Global AIDS Update (2018) Miles to Go Closing Gaps Breaking Barriers Righting Injustices. 2018.

2. UNAIDS (2017) UNAIDS Data.

3. Wanyenze RK, Kamya MR, Fatch R, Mayanja-Kizza H, Baveewo S et al. (2011) Missed Opportunities for HIV Testing and Late-Stage Diagnosis among HIV-Infected Patients in Uganda. PLoS One 6.

4. UNAIDS (2014) A short Technical Update on Self-Testing for HIV. Joint United Nations Programme on HIV/AIDS World Health Organization.

5. UNAIDS/WHO (2010) Towards universal access-scaling up priority HIV/AIDS interventions in the health sector-progress report. World Health Organization: Geneva.

6. UNAIDS, Global AIDS update (2019) Communities at the centre: Defending rights, breaking barriers, Reaching people with HIV services.

7. Staveteig S, Wang S, Hwad SK, Bradley SEK, Nybro E et al. (2013). Demographic Patterns of HIV Testing Uptake in sub-Saharan Africa, B. Robey, Editor. Calverton, Maryland, USA: ICF International.

8. Mukolo A, Blevins M, Victor B, Paulin HN, Vaz LM et al. (2013) Community stigma endorsement and voluntary counseling and testing behavior and attitudes among female heads of household in Zambezia Province, Mozambique. BMC Public Health 13: 1155.

9. Njau B, Ostermann J, Brown D, Muhlbacher A, Reddy E et al. (2014) HIV testing preferences in Tanzania: a qualitative exploration of the importance of confidentiality, accessibility, and quality of service. BMC Public Health 14: 838.

10. Ostermann J, Njau B, Brown DS, Muhlbacher A, Thielman N (2014) Heterogeneous HIV testing preferences in an urban setting in Tanzania: results from a discrete choice experiment. PLoS One 9: 2100.

11. Musheke M, Ntalasha H, Gari S, McKenzie O, Bond V et al. (2013) A systematic review of qualitative findings on factors enabling and deterring uptake of HIV testing in Sub-Saharan Africa. BMC Public Health, 13: 220.

12. Morin SF, Khumalo-Sakutukwa G, Charlebois ED, Routh J, Fritz K et al. (2006) Removing barriers to knowing HIV status: same-day mobile HIV testing in Zimbabwe. Journal of Acquired Immune Deficiency Syndromes. 41: 218-24.

13. Negin J, Wariero J, Mutuo P, Jan S, Pronyk P et al. (2009) Feasibility, acceptability and cost of home-based HIV testing in rural Kenya. Tropical Medicine and International Health 14: 849-55.

14. Ahmed S, Delaney K, Villalba-Diebold P, Aliyu G, Constantine N et al. (2013) HIV counseling and testing and access-to-care needs of populations most-at-risk for HIV in Nigeria. AIDS care 25: 85-94.

15. TANZANIA HIV IMPACT SURVEY (THIS) 2016-2017 (2017) PRELIMINARY FINDINGS. Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) and the Ministry of Health (MoH) Zanzibar through the National Bureau of Statistics (NBS) and the Office of Chief Government Statistician (OCGS): Dar-es-Salaam, Tanzania 1-6.

16. Njau B, Watt MH, Ostermann J, Manongi R, Sikkema KJ et al. (2012) Perceived acceptability of home-based couples' voluntary HIV counseling and testing in Northern Tanzania. AIDS Care 24: 413-9.

17. Morfaw F, Mbuagbaw L, Thabane L, Rodrigues C, Wunderlich AP et al. (2013) Male involvement in prevention programs of mother to child transmission of HIV: a systematic review to identify barriers and facilitators. Syst Rev 2: 5.

18. Matovu JKB, Kisa R, Buregyeya E, Chemusto H, Mugerwa S et al. (2018) 'If I had not taken it [HIVST kit] home, my husband would not have come to the facility to test for HIV': HIV self-testing perceptions, delivery strategies, and post-test experiences among pregnant women and their male partners in Central Uganda. Global Health Action 11: 1503784.27

19. Choko AT, Fielding K, Stallard N, Maheswaran H, Lepine A et al. (2017) Investigating interventions to increase uptake of HIV testing and linkage into care or prevention for male partners of pregnant women in antenatal clinics in Blantyre, Malawi: study protocol for a cluster randomised trial. Trials 18: 349.

20. Choko AT, Kumwenda MK, Johnson CC, Sakala DW, Chikalipo MC et al. (2017) Acceptability of woman-delivered HIV self--testing to the male partner, and additional interventions: a qualitative study of antenatal care participants in Malawi. Journal of the International AIDS Society 20: 1-10.

21. Kumwenda M, Munthali A, Phiri M, Mwale D, Gutteberg T et al. (2014) Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. AIDS Behavior 18 Suppl 4: S396-404.

22. Conserve DF, Alemu D, Yamanis T, Maman S, Kajula L et al. (2018) "He Told Me to Check My Health": A Qualitative Exploration of Social Network Influence on Men's HIV Testing Behavior and HIV Self-Testing Willingness in Tanzania. American Journal of Men's Health.

23. Conserve DF, Muessig KE, Maboko LL, Shirima S, Kilonzo MN et al. (2018) Mate Yako Afya Yako: Formative research to develop the Tanzania HIV self-testing education and promotion (Tanzania STEP) project for men. PLoS ONE.

24. The IeDEA and ART cohort collaborations (2014) Immunodeficiency at the start of combination antiretroviral therapy in low-, middle- and high-income countries. Journal of Acquired Immune Deficiency Syndromes 65: e8-e16.

25. WHO (2016) Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services, World Health Organization, Geneva 27, Switzerland: France 1-104.

26. Kalibala S, Tun W, Cherutich P, Nganga A, Oweya E et al. (2014) Factors associated with acceptability of HIV self-testing among health care workers in Kenya. AIDS Behavior l4: S405-14.

27. Thirumurthy H, Hayashi K, Linnemayr S, Vreeman RC, Levin IP et al. (2016) Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. Lancet HIV 3: e266-74.

28. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S et al. (2015) Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study. PLoS Medicine 12: e1001873.

29. Brown B, Folayan MO, Imosili A, Durueke F, Amuamuziam A (2015) HIV self-testing in Nigeria: Public opinions and perspectives. Global Public Health 10: 354-65.

30. Asiimwe S, Oloya J, Song X, Whalen CC et al. (2014) Accuracy of un-supervised versus provider-supervised self-administered HIV testing in Uganda: A randomized implementation trial. AIDS Behavior 18: 2477-84.

31. Jennings L, Conserve DF, Merrill J, Kajula L, Iwelunmor J et al. (2017) Perceived Cost Advantages and Disadvantages of

Purchasing HIV Self- Testing Kits among Urban Tanzanian Men: An Inductive Content Analysis. Journal of AIDS & Clinical Research 08.

32. Conserve DF, Kajula L, Yamanis T, Maman S (2016) Formative Research to Develop Human Immunodeficiency Virus (HIV) Self-Testing Intervention Among Networks of Men in Dar es Salaam, Tanzania: A Mixed Methods Approach. Open Forum Infectious Diseases 3: 518.

33. Tonen-Wolyec S, Batina-Agasa S, Muwonga J, N'kulu FF, Bouassa RM et al. (2018) Evaluation of the practicability and virological performance of finger-stick whole blood HIV self-testing in French-speaking sub-Saharan Africa. PLoS One 13: e0189475.

34. Mokgatle MM, Madiba S (2017) High Acceptability of HIV Self-Testing among Technical Vocational Education and Training College Students in Gauteng and North West Province: What Are the Implications for the Scale Up in South Africa? PLoS One 12: e0169765.

35. Pant Pai N, Behlim T, Abrahams L, Vadnais C, Shivkumar S et al. (2013) Will an Unsupervised Self-Testing Strategy for HIV Work in Health Care Workers of South Africa? A Cross Sectional Pilot Feasibility Study. PLoS One 8.

36. Makusha T , Knight L, Taegtmeyer M, Tulloch O, Davids A et al.(2015) HIV Self-Testing Could "Revolutionize Testing in South Africa, but It Has Got to Be Done Properly": Perceptions of Key Stakeholders. PLoS One 10: e0122783.

37. Krause J, Subklew-Sehume F, Kenyon C, Colebunders R et al. (2013) Acceptability of HIV self-testing: a systematic literature review. BMC Public Health 13: 1-19.

38. WHO (2015) Consolidated guidelines on HIV testing services. Geneva: World Health Organization.

39. Spielberg F, Levine RO, Weaver M (2004) Self-testing for HIV: a new option for HIV prevention? Lancet Infectious Diseases 4: 640-6.

40. Cambiano V, Ford D, Mabugu T, Napierala Mavedzenge S, Miners A et al. (2015) Assessment of the Potential Impact and Cost-effectiveness of Self-Testing for HIV in Low-Income Countries. J Infect Dis 212: 570-7.

41. Neuman M, Indravudh P, Chilongosi R, d'Elbee M, Desmond N et al. (2018) The effectiveness and cost-effectiveness of community-based lay distribution of HIV self-tests in increasing uptake of HIV testing among adults in rural Malawi and rural and peri-urban Zambia: protocol for STAR (self-testing for Africa) cluster randomized evaluations. BMC Public Health, 18: 1234.

42. Hatzold K Gudukeya S, Mutseta MN, Chilongosi R, Nalubamba M et al. (2019) HIV self-testing: breaking the barriers to uptake of testing among men and adolescents in sub-Saharan Africa, experiences from STAR demonstration projects in Malawi, Zambia and Zimbabwe. J Int AIDS Soc 1: e25244.

43. US Food and Drug Administration (2012) OraQuick In-Home HIV test summary of safety and effectiveness. Silver Spring: FDA.

44. Prazuck T, Karon S, Gubavu C, Andre J, Legall J M et al. (2016) A Finger-Stick Whole-Blood HIV Self- Test as an HIV Screening Tool Adapted to the General Public, PloS One 11: e0146755.

45. World Health Organization & UNITAID (2016) Technology Landscape, HIV rapid diagnostic tests for self-testing.

46. World Health Organization (2016) Technical specification series for submission to WHO Prequalification-Diagnostic Assessment. TSS-1: Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional and/or self-testing.

47. WHO (2016) WHO recommends HIV self-testing Policy brief.

48. van Rooyen H, Tulloch O, Mukoma W, Makusha T, Chepuka L et al. (2015) What are the constraints and opportunities for HIVST scale-up in Africa? Evidence from Kenya, Malawi and South Africa. Journal of the International Aids Society 18: 19445.

49. Mavedzenge SN, Baggaley R, Corbett E L (2013) A review of self-testing for HIV: research and policy priorities in a new era of HIV prevention. Clinical Infectious Diseases 57: 126-38.

50. Gagnon M, French M, Hebert Y (2018) The HIV self-testing debate: where do we stand? BMC International Health and Human Rights 18: 5.

51. TACAIDS (2018) BOTTLENECKS AND CATCH-UP PLAN FOR ENGAGEMENT OF ADULT MEN AND ADOLESCENT BOYS IN HIV COUNSELING AND TESTING IN TANZANIA.

52. National Bureau of Statistics (2012) Tanzania Population and Housing Census 2012, Dar es Salaam.

53. Ostermann J, Whetten K, Reddy E, Pence B, Weinhold A et al. (2014) Treatment retention and care transitions during and after the scale-up of HIV care and treatment in Northern Tanzania. AIDS Care 26: 1352-8.

54. Ao TT, Sam NE, Masenga EJ, Seage GR, Kapiga SH et al. (2006) Human Immunodeficiency Virus Type 1 Among Bar and Hotel Workers in Northern Tanzania: The Role of Alcohol, Sexual Behavior, and Herpes Simplex Virus Type 2. Sexually Transmitted Diseases 33: 163-9.

55. Kapiga SH, Sam NE , Shao JF, Renjifo B, Massenga EJ et al. (2002) HIV-1 Epidermic Among Female Bar Workers and Hotel Workers in Northern Tanzania: Risk Factors and Opportunities for Prevention. Journal of Acquired Immune Deficiency Syndromes 29: 409-17.

56. Ostermann J, Njau B, Mtuy T, Brown DS, Muhlbacher A et al. (2015) One size does not fit all: HIV testing preferences differ among high-risk groups in Northern Tanzania. AIDS Care 27: 595-603.

57. Peaty D (2010) Kilimanjaro Tourism and What It Means for Local Porters and for the local Enviroment. Journal of Ritsumeikan Social Sciences and Humanities 4: 1-12.

58. Lyamuya JE, Njau B, Damian DJ, Mtuy T (2017) Sociodemographic and Other Characteristics Associated With Behavioural Risk Factors of HIV Infection Among Male Mountain-Climbing Porters in Kilimanjaro Region, Tanzania. East African Health Research Journal 1-8.

59. Lenth R (2001) Some Practical Guidelines for Effective Sample size Determination. The American Statistician 55: 187-193.

60. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S et al. (2011) The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. PLoS Medicine 8: e1001102.

61. Partners HSV-2/HIV-1 Transmission Study Team (2009) Characteristics of HIV-1 Discordant Couples Enrolled in a Trial of HSV-2 Suppression to Reduce HIV-1 Transmission: The Partners Study. PLoS ONE 4: e5272.

62. Kasprzyk D, Montano D (2007) Application of an integrated behavioral model to understand HIV prevention behavior of high--risk men in rural Zimbabwe.

63. Baranowski T, Perry C, Parcel G (2002) How individuals, environments, and health behavior interacts: Social Cognitive Theo-

ry. In K. Glanz, B. Rimer & F. M. Lewis (Eds.), Health Behavior and Health Education: Theory, research and practice (3rd ed., pp. 165-184). San Francisco: Jossey-Bass.

64. Bandura A (2006) GUIDE FOR CONSTRUCTING SELF-EFFICACY SCALES, in Self-Efficacy Beliefs of Adolescents, A. Bandura, Editor, Information Age Publishing 307-37.

65. Oldenburg B, Glanz K (2008) Diffusion of Innovations, in Health Behaviour and Health Education: Theories, research and practice., K. In Glanz, FM. Lewis, and K. Viswanath, Editors, Jossey-Bass: San Francisco 313-33.

66. WHO (2013) Report on the first international symposium on self-testing for HIV: the Legal, ethical, gender, human rights and public health implication of HIV self-testing scale-up, World Health Organization.

67. Mavedzenge SN, Baggaley R, Lo YR, Corbett L (2011) HIV self-testing among health workers: a review of the literature and discussion of current practices, issues and options for increasing access to HIV testing in Sub-Saharan Africa.

68. WHO (2014) supplement to the consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, recommendations for a public health approach. WHO: Geneva: 12-7.

69. Njau B, Werfalli M, Abdullahi L, Mathews C (2016). A systematic review on uptake and yield of HIV self-testing among adults in Africa.

70. Njau B, Colvin C, Lisasi E, Damian DJ, Mushi D et al (2019) A systematic review of qualitative evidence on factors enabling and deterring uptake of HIV self-testing in Africa. BMC Public Health 1289: 1-16.30

71. Njau B , Lisasi E, Damian DJ, Mushi DL, Boulle A et al (2020) Feasibility of an HIV self-testing intervention: a formative qualitative study among individuals, community leaders, and HIV testing experts in Northern Tanzania. BMC Public Health 20: 490.

72. Njau B, Damian DJ, Lisasi E, Mushi D, Mathews C (2023) A theory-based behaviour change intervention to increase HIV Self-Testing uptake and linkage to HIV prevention, care and treatment for hard-to-reach populations in northern Tanzania. Tanzania Journal of Health Research 24: 121-37.

73. Cronbach LJ (1957) Coefficient alpha and the internal structure of tests. Pyschometrika 16: 297-334.

74. Kaiser H (1970) A Second generation Little Jiffy. Psycometrika 35: 401-15.

75. Kaiser H (1974) An index of factorial simplicity. Psycometrika 39: 31-36.

76. Bartlett MS (1954) A note on the multiplying factors for various chi-square approximations. J Roy Stat Soc Stat Soc, 16(Series B) 296-8.

77. Catell RB (1966) The scree test for numbers of factors. Multivariate Behaviour Research 1: 245-76.

78. TENGIA-KESSY A, LYAMUYA DE (2018) Utilisation of voluntary counseling and testing services among bar waitresses in Kinondoni District, Dar es Salaam, Tanzania. Tanzania Journal of Health Research 20: 1-8.

79. Hector J, Davies MA, Dekker-Boersema J, Aly MM, Abdalad CCA et al. (2018) Acceptability and performance of a directly assisted oral HIV self-testing intervention in adolescents in rural Mozambique. PLoS One 13: e0195391.

80. Kurth AE, Cleland CM, Chhun N, Sidle JE, Were E et al. (2016) Accuracy and Acceptability of Oral Fluid HIV Self-Testing in a

General Adult Population in Kenya. AIDS Behavior 20: 870-9.

81. Ng OT, Chow ANL, Lee VJ, Chen MIC, Win MK et al. (2012) Accuracy and User-Acceptability of HIV Self-Testing Using an Oral Fluid-Based HIV Rapid Test. PLoS ONE 7: e45168.

82. Peck RB, Lim JM, van Rooyen H, Mukoma W, Chepuka L et al. (2014) What should the ideal HIV self-test look like? A usability study of test prototypes in unsupervised HIV self-testing in Kenya, Malawi, and South Africa. AIDS Behavior l 4: S422-32.

83. Zanolini A Chipungu J, Vinikoor MJ, Bosomprah S, Mafwenko M et al. (2017) HIV Self-Testing in Lusaka Province, Zambia: Acceptability, Comprehension of Testing Instructions, and Individual Preferences for Self-Test Kit Distribution in a Population-Based Sample of Adolescents and Adults. AIDS Research and Human Retroviruses.

84. Chipungu J Bosomprah S, Zanolini A, Thimurthy H, Chilengi R et al. (2017) Understanding linkage to care with HIV self-test approach in Lusaka, Zambia - A mixed method approach. PLoS One 12: p. e0187998.

85. Lee VJ , Tan SC, Earnest A, Seong PS, Tan HH et al. (2007) User acceptability and feasibility of self-testing with HIV rapid tests. Journal of Acquired Immune Deficiency Syndromes 45: 449-53.

86. Figueroa C, Johnson C, Ford N, Sands A, Dalal S et al. (2018) Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis.The Lancet HIV.

87. Pai NP, Sharma J, Shivkumar S, Pillay S, Vadnais C et al. (2013) Supervised and Unsupervised Self-Testing for HIV in High-and Low- Risk Populations: A Systematic Review. PLoS Medicine 10: e1001414.

88. Sarkar A, Mburu G, Shivkumar PV, Sharma P, Campbell F et al. (2016) Feasibility of supervised self-testing using an oral fluid-based HIV rapid testing method: a cross-sectional, mixed method study among pregnant women in rural India. Journal of International AIDS Society 19: 20993.

89. Mugo PM, Micheni M, Shangala J, Hussein MH, Graham SM et al. (2017) Uptake and Acceptability of Oral HIV Self-Testing among Community Pharmacy Clients in Kenya: A Feasibility Study. PLoS One 12: e0170868. 31

90. Njau B,Werfalli M, Abdullahi L, Mathews C (2016) The effects of HIV self-testing on the uptake of HIV testing and linkage to antiretroviral treatment among adults in Africa: a systematic review protocol. Systematic Reviews 5: 1-8.

91. Johnson CC , Kennedy C, Fonner VA , Siegfried N, Figueroa C et al. (2017) Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. Journal of the International AIDS Society 20.

92. Sharma M, Ying R, Tarr G, Barnabas R (2015) Systematic review and meta-analysis of community and facility based HIV testing to address linkage to care gaps in sub-Saharan Africa. Nature 528: p. S77-85.

93. Suthar AB Ford N, Bachanas PJ, Wong VJ, Rajan JS et al. (2013)Towards Universal Voluntary HIV Testing and Counseling: A Systematic Review and Meta-Analysis of Community-Based Approaches. PLoS Medicine 10: e1001496.

94. Mahler HR, Kileo B, Curran K, Plotkin M, Adamu T et al. (2011) Voluntary Medical Male Circumcision: Matching Demand and Supply with Quality and Efficiency in a High-Volume Campaign in Iringa Region, Tanzania. PLoS Medicine 8: 1-8.

95. United Republic of Tanzania and Ministry of Health and Social Welfare and National AIDS Control Programme (2012) National Guidelines for Management of HIV and AIDS. Dar es Salaam, Tanzania.

96. Indravudh PP, Sibanda EL, d'Elbee M, Kumwenda MK, Ringwald B et al. (2017) 'I will choose when to test, where I want to test': investigating young people's preferences for HIV self-testing in Malawi and Zimbabwe. AIDS 3: S203-12.

97. Indravudh PP, Choko AT, Corbett EL (2018) Scaling up HIV self-testing in sub-Saharan Africa: a review of technology, policy and evidence. Current Opinion Infectious Diseases 31: 14-2

98. Knight L, Makusha T, Lim J, Peck R, Taegtmeyer M et al. (2017) "I think it is right": a qualitative exploration of the acceptability and desired future use of oral swab and finger-prick HIV self-tests by lay users in KwaZulu-Natal, South Africa. BMC Research Notes 10: 486.

99. Kasprzyk D, Montana DE, Fishbein M (1998) Application of an Integrated Behavioural Model to Predict Condom Use: A prospective study among High HIV Risk Groups. Journal of Applied Social Psychology 28: 1557-83.

100. Montaño DE, Kasprzyk D, Hamilton DT, Tshimanga M, Gorn G (2014) Evidence-Based Identification of Key Beliefs Explaining Adult Male Circumcision Motivation in Zimbabwe: Targets for Behavior Change Messaging. AIDS Behavior 18: 885-904.

101. Scott-Sheldon LAJ, Huedo-Medina TB, Warren MR, Johnson BT, Carey MP et al. (2011) Efficacy of Behavioral Interventions to Increase Condom Use and Reduce Sexually Transmitted Infections: A Meta-Analysis, 1991 to 2010. Journal of Acquired Immune Deficiency Syndromes 58.

102. Fishbein M, Cappella JN (2006) The role of theory in developing effective health ommunications. Journal of Communication 56: S1-S17.

103. Critical Appraisal Skills Programme (2010) Critical Appraisal Skills Programme 10 questions to help you make sense of qualitative research. England: Critical Appraisals Skills Programme.

104. Effective Practice and Organization of Care (2009) Cochrane Effective Practice and Organization of Care Group. Risk of bias for studies with a separate control group (RCTs, CCTs, CBAs).

105. Johnston C, Orem J, Okuku F, Kalinaki M, Saracino M et al. (2009) Impact of HIV Infection and Kaposi Sarcoma on Human Herpes virus-8 Mucosal Replication and Dissemination in Uganda. PLoS ONE 4.