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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

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Abstract

Background: HIV Self-Testing (HIVST) has the potential to circumvent barriers associated with conventional, facility-based HIV testing services. To increase the uptake of HIVST among hard-to-reach populations, we need effective HIVST implementation strategies based on theory and evidence. In this article, we describe the development of a behaviour change intervention (BCI) using the PRECEDE -PROCEED model; the Capability, Opportunity, Motivation, and Behaviour (COM_B) model and the Behavior Change Wheel (BCW). We also describe the acceptability and feasibility of the BCI and the fidelity of its implementation.

Methods: Content and delivery were informed by **a** systematic review, qualitative syntheses and formative exploration of barriers and facilitators for the uptake of HIVST among hard-to-reach populations in northern Tanzania. Additional inputs were received from members of a local community advisory board (CAB). An uncontrolled before-after study design was conducted between March 2018 (pre-intervention phase) and July 2018 (post-intervention phase). The acceptability and feasibility of the BCI were assessed qualitatively among ten conveniently selected participants. The fidelity of implementation was assessed using direct observation of ten-trained PEs using a pre-defined index checklist.

Results: The resulting intervention was two individual sessions delivered by ten-trained peer –educators. Participants perceived the BCI as acceptable and feasible to increase HIVST uptake among hard-to-reach populations. Ratings for the overall intervention sessions ranged from 4.3 to 4.8(max= 5). Overall ratings on materials ranged from 4.7 to 4.8(max =5). The overall mean adherence score was 33.5(SD 3.2) ranging from 20 to 38. The overall mean performance score was 15.5 (SD 1.9) ranging from 12 to 18.

Conclusions: The present findings suggest the BCI was well accepted among hard-to-reach populations and feasible in an urban setting in northern Tanzania. The BCI was implemented with moderate to high levels of fidelity by trained PEs.

Keywords: Intervention design, Intervention development, Theory use, HIV Self-testing, Tanzania.

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Introduction

Implementation science suggests that behaviour change interventions (BCIs) grounded on theories are effective at the individual, community and population levels (Davis et al., 2015; Villalobos Dintrans et al., 2019). However, the effectiveness of BCIs is relatively modest with considerable heterogeneity of short-term and long-term effects. Besides, ineffective interventions do exist in implementation science literature (Michie et al., 2013). Additionally, there is a dearth of information related to the fidelity of the implementation of BCI in the implementation of science literature (Davis et al., 2015; Villalobos Dintrans et al., 2019). The query as to whether BCI that are overtly grounded in theory are more effective than those that are not is complex (Davis et al., 2015). One key factor that may explain the query is the poor application of theory (Davis et al., 2015; Villalobos Dintrans et al., 2019).

There is a lack of information on the links between behaviour change techniques and theoretical constructs in most theory-based interventions, or whether all the constructs were targeted by behaviour change techniques may influence the effectiveness of the BCI (Davis et al., 2015; Villalobos Dintrans et al., 2019). An alternative explanation may be the inappropriate selection of theory. An appropriate theory that is effective to bring about a specific behaviour change is very important to bring about the expected behaviour change (Davis et al., 2015; Villalobos Dintrans et al., 2019). To circumvent this fundamental limitation described above, this BCI was grounded on the Integrated Behavior Model.

Guidance for developing complex interventions such as those focusing on the uptake of HIV testing advocates the use of behavioural change theories in the intervention development process (Godin et al., 2008; Hoffmann et al., 2014) because interventions are more likely to be effective if they target causal determinants of behaviour and behaviour change. To understand the causal mechanisms mentioned above, it is imperative to use Behavioral change theories (Godin et al., 2008).

Many intervention studies, however, do not report an adequate description of justification, the development procedures and sufficient depiction of the intervention components, methods of delivery and the context in which it is implemented to support replication and/or modification of interventions (Hoffmann et al., 2014). The observed gap may be explained by poor planning, lack of a link to behavioural theories and lack of formative research involving potential intervention users (Godin et al., 2008).

To avoid the poor planning mentioned above, this study used the PRECEDE-PROCEED model to guide the planning, design and development of the intervention. In brief, the PRECEDE-PROCEED model is a comprehensive planning and evaluation tool for designing interventions.

The model is made up of two key concepts: Precede –refers to predisposing, reinforcing, and enabling constructs in educational diagnosis and evaluation. Proceed refers to policy, regulatory, and organizational constructs in educational and environmental development. The model is divided into six phases, providing step-by-step guidance on intervention planning, designing, development, and aspects for intervention evaluation (Glanz et al., 2008). For the purpose of this article we present the four phases of the PRECEDE model as depicted in Figure 1.

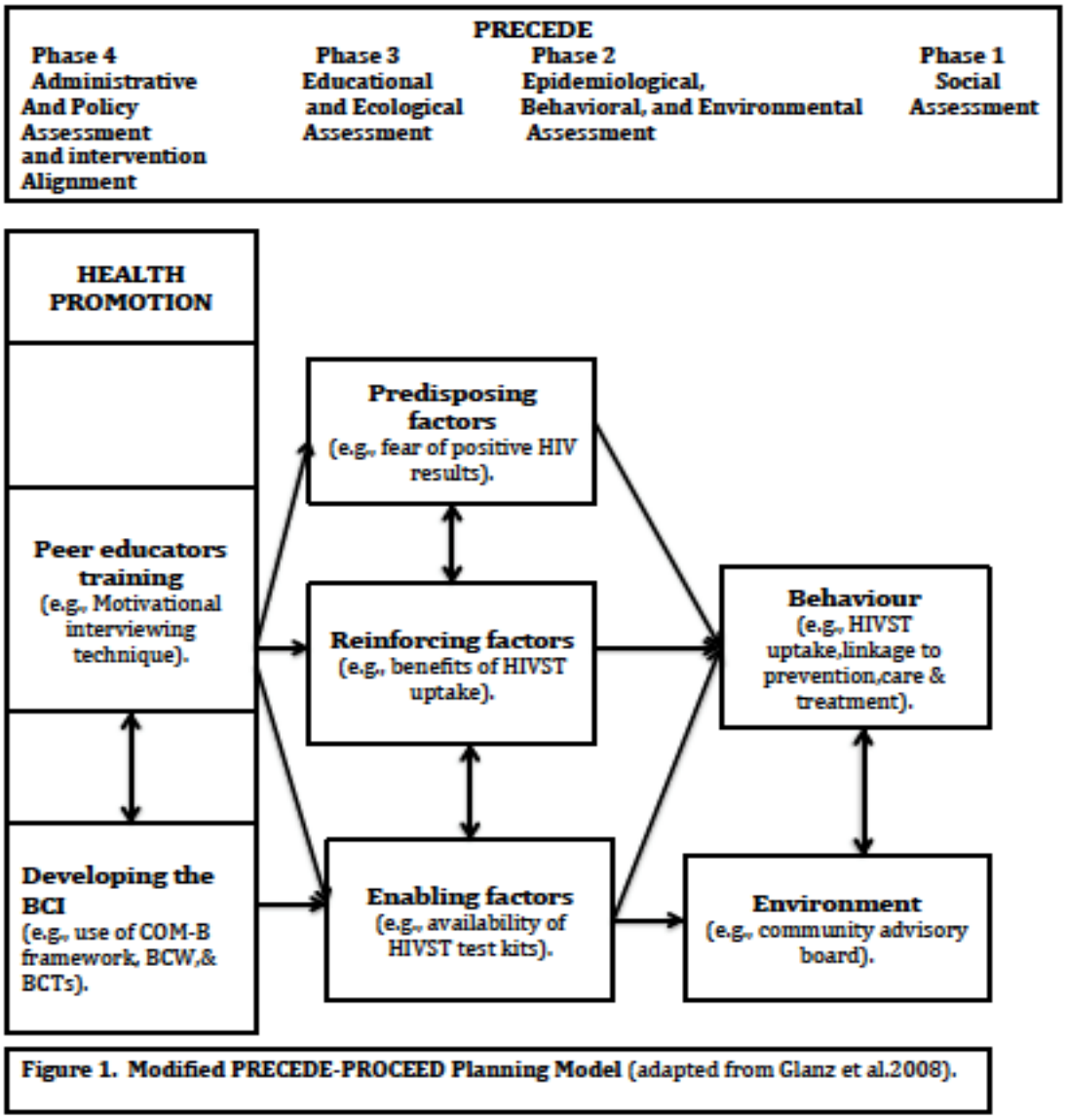

Figure 1. Modified PRECEDE-PROCEED Planning Model (adapted from Glanz et al.2008).

The PREEDE-PROCEED model, Capability-Opportunity-Motivation and Behaviour (COM-B) framework, and the Behaviour Change Wheel (Michie et al., 2011), were used to guide, design and develop a theory-based BCI for Female bar workers (FBWs), and Male mountain climbing porters (MMCP) in northern Tanzania. At present, there is a dearth of information on the acceptability and feasibility of a theory-based behaviour change intervention (BCI) to increase HIVST uptake and linkage to HIV prevention, care and treatment among FBWs and MMCPs in northern Tanzania.
This study also aimed to fill that gap by presenting findings of a process evaluation on the acceptability and feasibility of the BCI and its fidelity of its implementation among hard to reach populations in northern Tanzania.

Methods

Study design

An uncontrolled before-after study design was conducted between March 2018 (pre-intervention phase) and July 2018 (post-intervention phase). A minimum sample of 170 participants was estimated using a confidence interval approach (Lenth, 2001). Assuming HIVST uptake of 87.2% or greater, a significance margin error (ME) of 5% and a confidence level of 95%, with 80 % power, we calculated that a sample of 170 participants were required (Choko et al., 2011). In addition, 10 participants (MCPs = 5; FBWs =5) were conveniently selected to participate in exit interviews to assess acceptability, feasibility, and fidelity of its implementation.

Study participants

We recruited participants who were 18 years of age or older at the time of enrollment, and who self-reported an HIV-negative status and had not had an HIV test in the past 3 months or self-reported that their HIV status was unknown. 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 the study. Participants providing written consent were sent back to the trained PEs to schedule attendance at the first intervention session.

Study overview

To facilitate reproducibility of the intervention, recommendations provided by the TIDieR were used to guide the development of descriptions of the BCI (additional file 1).The PRECEDE-PROCEED model was used as a 'road map' and the main purpose was to provide a structure for applying the COM-B framework, and the BCW systematically for guidance on the design and development of the BCI for HIVST uptake among hard-to-reach populations in northern Tanzania. The design and development of this intervention proceeded in four phases: 1) identification of evidence-gap on HIVST uptake, 2) identification of behavioral or environmental determinants, 3) educational and ecological assessments, and 4) intervention development.

Methods for phase 1: Identifying the evidence-practice gap on HIVST uptake

In phase 1 the aim was to identify the evidence-practice gap in the existing social context related to the current HIV testing practices and factors that may affect HIVST uptake and linkage to HIV prevention, care and treatment (Njau et al., 2021). Initial intervention development was guided by findings from a systematic review to determine the effects of HIVST on the uptake of HIV testing and yield of new HIV positive diagnoses, social harms and linkage to antiretroviral treatment (Njau et al., 2021), and an evidence synthesis on experiences of HIVST and in-depth perspectives of the factors that facilitate or hinder HIVST uptake among adults in Africa (Njau et al., 2019). The research team used the evidence synthesis findings to understand the existing social context related to current HIV testing practices and to identify and evaluate factors that may affect HIVST uptake and linkage to HIV prevention, care and treatment (Njau et al., 2019).

Methods for phase 2: Identifying epidemiological, behavioural or environmental determinants

After identifying the evidence - practice gap in HIVST uptake in the study settings, the research team conducted a formative study with a variety of stakeholders to explore their understanding about the motivation and beliefs of the community towards HIVST uptake and target populations' attitudes, beliefs, social norms, personal agency, barriers to and facilitators for HIVST uptake (Njau et al., 2020). Fifteen community members attended a one-day meeting including representatives from the municipal department of health (n =2), community health workers (n= 3), HIV counselors (n=2), people living with HIV (n=3), youth groups (n=3), and tour guides (n = 2).

Methods for phase 3: Educational and ecological assessment

In phase 3, the focus was to combine the key specific beliefs, barriers and facilitators, grouped by COM-B framework to identify components and potential behaviour change techniques (BCTs) for the BCI. In the COM-B, the "capability", "opportunity", and "motivation" are three layers making-up the model and are essential determinants of a " behavior" outcome (Michie et al., 2011).

In this BCI capability included description on how to use HIVST test kits, and a 5-minute video show on how to use an oral-based HIV test; opportunity included: a rehearsal on how to use HIVST test kits, and motivation included moderation of negative feelings about fear of positive results, adverse effects post HIVST testing and fear of seeing blood/and needle pricks, benefits of HIVST and advantages of testing or disadvantages of not testing, and social consequences of using or not using HIVST. Also motivation included emphasis on significant others' approval of using HIVST,

provision of feedback on performance on how to use HIVST test kits, and focus on past success of life experiences. The behavioral outcome included uptake of HIVST and linkage to HIV prevention, care and treatment (see Table 1.)

The research team used the behaviour change technique taxonomy (BCTTv1) to select components of BCTs, and the Behaviour Change Wheel [BCW] to select the intervention functions (Michie et al., 2011). In this study two researchers, Bernard Njau [BN], and Ester Lisasi [EL] applied the BCCTv1 approach to select components of BCTs in three steps.

Two reviewers mapped the identified modifiable barriers and facilitators for HIVST uptake, to appropriate BCTs using the behaviour change wheel (BCW) framework developed by Michie et al. (Michie et al., 2011). They also selected five (5) intervention functions from a list of nine intervention functions included in the BCW. The five intervention functions were (a) education, (b) enablement (c) training, (d) modeling, and (e) persuasion (Michie et al., 2011). All selected BCTs and functions are summarized in Table 1.

Table 1: Intervention components, content and mechanisms of action using the BCT taxonomy (v1); behavior change wheel; capability, motivation, and behavior model (COM-B).

Intervention component	**Intervention content**		**Mechanisms of action**
	BCTs	Functions	COM-B
11:2. Peer-educators help participants to moderate negative feelings about fear of positive results, adverse effects post HIVST testing and fear of seeing blood/and needle pricks, with alternative positive thoughts or situational role reversal (e.g., use of oral HIVST tests).	**11.2.** Regulate negative emotions	Education [1], Enablement [2]	Ref M
4:1. Descriptions on how to use the HIVST test kits were provided to participants.	**4:1.** Instruction on how to perform the behaviour	Education, Training [3]	Psy C
5:3. Peer educators provide information about the benefits of HIVST and advantages of testing or disadvantages of not testing for HIV, focusing on the social consequences if the person does or does not perform the HIVST.	**5:3** Information about social consequences	Education	Ref M
6:3. Peer-educators provide about what significant others (e.g., parents, peers, relatives, friends, etc.) think about the person's HIV testing behaviour and emphasize significant other's approve of using HIVST.	**6:3** Information about others' approval	Persuasion [4]	Ref M
6:1. Peer-educators showed a 5-minutes video on how to use an oral-based HIV test.	**6:1** Demonstration of the behaviour	Education, Training, Modeling [5]	Phys C, Psy C

2:7. Peer-educators providing feedback to participants on how they performed on how to use the HIV self-test kits.	**2:7** Feedback on the outcome(s)	Persuasion	Ref M
15:3. Peer-educators help the person to focus on the past success of life experience rather than on failures.	**15:3** Focus of past success	Persuasion	Ref M
8:1. Peer-educators ask the person to rehearse HIV self-testing after viewing the video.	**8:1** Prompt practice	Education	Phys O
1 = Increasing knowledge or understanding, 2= Increasing means/reducing barriers to increase capability or opportunity, 3= Imparting skills, 4= Using communication to induce positive or negative feelings or stimulate action., and 5= Providing an example for people to aspire to or imitate.			
COM-B abbreviations: Ref M: reflective motivation, Psy C: psychological capability, Phys C: physical capability, Phys O: physical opportunity.			

Methods for Phase 4: Developing the BCI

The research team used the information collected from phases 1-3 and the HIV testing experiences in the study setting to develop a workbook (additional file 2) to assist the trained peer-educators to implement the BCI. In this phase, the focus was to align the component of the intervention, intervention functions and the BCTs at the micro-level to develop an engaging and informative BCI tailored for FBWs and MMCPs. The topics of session one focused on how to alleviate negative feelings about fears associated with HIVST, decrease perceptions of barriers related to HIVST, reinforce enablers for HIVST, correct misconceptions about HIVST and reinforce subjective and descriptive norms associated with HIVST uptake.

Once the content and structure of the workbook were finalized, IEC materials (i.e. photographic materials, leaflets and video) were compiled. The resources included photographic materials and interactive cards and a take-home leaflet. The IEC materials focused on the topics covered in the workbook. The take-home leaflet was a copy of the pictorial instructions on how to do HIVST in Swahili, meant for reinforcement of the information delivered in the sessions (additional file 3).

All the IEC materials were pre-tested for comprehension, appeal, and emotional impact among 10 (5 men; 5 female) representatives of the target populations. Feedback from the pre-testing was incorporated to improve the IEC materials.

The BCI comprised of an educational strategy, a video on HIVST and a demonstration and simulation on how to use OraQuick® rapid HIV 1/2 antibody test. The intervention consisted of 2 sessions, was delivered by trained PEs at a research centre within Moshi Municipality. The session duration ranged from 45 minutes to 60 minutes. Sessions were one-on-one between the PE and participant using motivational interviewing were conducted.

In session one (duration = 60 minutes), the PE presented: (i) information about routes of transmission of HIV to alleviate HIV related misconceptions and (ii) barriers to and facilitators for HIV testing. Then, the PE initiated a discussion to engage in conversation with the participant about HIVST, including its accuracy in detecting antibodies against HIV and on how to use the oral-fluid HIVST kits.

This also allowed the participant to learn about the HIVST and clarify any misconceptions about self-testing for HIV. At the end of session one, the PE scheduled an appointment with the participant for session two within one week.

In session two (duration = 45 minutes), the PE introduced the oral-fluid HIVST under the supervision of the PI [BN]. The study used OraQuick® rapid HIV 1/2 antibody test (OraSure Technologies, Bethlehem, PA, USA), a lateral-flow, immuno-chromatographic, second-generation, oral-fluid assay detecting antibodies to HIV-1 and HIV-2.

Acceptability of the intervention

Acceptability was assessed qualitatively from 10 (MCPs = 5; FBWs =5) conveniently selected study participants. Feedback from participants was obtained for individual sessions (following sessions 1-2) and intervention overall (post-test follow-up) through an exit interviews. An in-depth interview guide was used to collect information on acceptability and feasibility of the BCI, and fidelity of its implementation.

Feasibility of the intervention

Participants assessed the feasibility of the BCI at the end of session 2 by rating the intervention sessions and materials. The ratings were on intervention sessions and materials (e.g. " Overall, the contents of the sessions were understandable") and were assessed on the scale from 1 to 5 (1 "I disagree" to 5 " I agree").

Fidelity of implementation

Fidelity of implementation focused on adherence (i.e. extent of intervention implementation as planned), recruitment of participants (i.e. procedures used to approach participants), dose-delivered (i.e. sessions completeness), dose received (i.e. the extent of participants' exposure to the intervention) and reach (i.e. participants' participation rate). Adherence was scored from 0 to 2 on 19 aspects of intervention content (range score was 0-38). A score of 0 indicated that the aspect was not implemented, a score of 1 indicated that the aspect was partially implemented and a score of 2 indicated that the aspect was completely implemented. The 19 aspects of the intervention content were grouped into 5 categories as follows: (i) Perceived barriers/facilitators for HIVST uptake (ii) myths around HIVST use (iii) self-confidence towards HIVST uptake (iv) positive or negative consequences of HIVST uptake and (v) skills of using Oral Quick HIVST test kits. PEs' performance on session facilitation was assessed by direct observation at a random sequence by an independent observer.

Their performance was scored from 0 to 2 on 9 aspects of session facilitation (range score was 0-18). A score of 0 indicated that the aspect was not implemented, a score of 1 indicated that aspect was partially implemented and a score of 2 indicated that the aspect was completely implemented. The 9 aspects of session facilitation were: building a friendly relationship with participants, presentation of session objectives, building on participants' experiences, providing reassurance to participants, eliciting and answering questions, listening carefully, checking to understand, eliciting feedback from participants and providing a clear conclusion of the sessions. Recruitment was assessed by the rate of response to invitations delivered to eligible participants. Attendance, length of sessions and retention were recorded by the PEs following each session. The first author (BN) assessed fidelity by direct-observation of PEs at random sequences using a pre-defined index checklist.

Data management

Qualitative analysis

Data were analyzed using content analysis (Erlingsson & Brysiewicz, 2017). In the first step, two coders listened to the voice recordings and read and re-read transcribed interviews to become familiar and to gain a general understanding of the data. Before analysis, identifying information was removed from the transcripts. While keeping focused on the aim and research question, the transcribed interviews were divided up into smaller parts as meaning units.

In the second step, the located meaning units were condensed further without losing the essential message of the meaning unit. The aim was to reduce the meaning units that were too large and included many meanings to smaller, manageable data. In the third step, the two coders developed codes that were descriptive labels for the meaning units. The codes were outlined in a codebook based on the meaning units. The aim was to identify connections between meaning units keeping focused on the data with the minimum interpretation of the content. The two coders combined their codebooks, adjusted and repeated coding, until they reached a consensus of the final codes.

In the final step, the codes were sorted into categories aiming to answer the questions: *who, what, when or where*? Codes were compared and appraised to determine which codes seemed to belong together, in order to form categories. Next, themes were generated from a category or categories to answer the questions: why, how, in what way, or by what means? The themes expressed underlying meaning and were formed by combining two or more categories. Findings are presented in the results sections with corresponding quotes.

Results

Phases 1 and 2

Local community advisory board meeting

The outline of the intervention was presented and feedback was sought on appropriate session length, mode of delivery and social and cultural acceptance of the components of the proposed intervention. The members used their HIV Testing Services (HTS) expertise and experiences to consider the practicability of delivery of the components of the intervention in the study setting. Discussions during the workshop elicited concrete feedback, which was used to modify the contents of the intervention.

The local stakeholders recommended: "***Wawezeshaji rika"***- a Swahili word for peer educators (PEs). Also, the stakeholders suggested that training topics for peer educators should cover the following (a) reasons for wanting to test, (b) consequences of not testing for HIV, (c) stigma related with HIV testing, (d) knowledge about HIVST, (e) benefits of HIVST (oral fluid test), (f) perceived barriers to/motivators to HIVST uptake, (g) myths about HIV/AIDS, (h) self-efficacy for HIVST uptake, (i) barriers to achieving linkage to prevention, care and treatment after HIVST, (j) types of family planning methods at HIV counseling and testing (HCT) services, and (k) benefits of VMMC.

Additional topics were: building self-confidence and skills on OraQuick ADVANCE rapid HIV-1/2 antibody test kits. Also, the local stakeholders listed the roles and responsibilities of PEs as follows (a) to provide correct information correctly to the participants (b) to make a proper follow-up of participants according to the study protocol (c) to keep all participants' personal information confidential and (d) to show respect to participants throughout the study. The roles and responsibilities of the participants were to (a) be respectful to PEs and other participants (b) be cooperative throughout the study (c) be fully engaged during the training and (d) keep all participants' personal information confidential.

Finally, the local stakeholders mentioned challenges for the implementation of HIVST that should be addressed as (a) fear of participants being seen by others while carrying the HIVST test kits in public (b) the English language used in the information package for instruction on how to use the HIVST test kits and (c) the sensitivity and privacy associated with HIV testing. It was recommended that brown envelopes should be used to carry the HIVST self-test kits, a Swahili version for instruction on how to use the HIVST test kits (additional file 3) should be available for participants and the intervention should be delivered on a 'one-on-one' format as opposed to a group format.

Peer –educators training

This study used opinion leaders (OLs) - persons who influence the opinions, attitudes, beliefs, motivations and behaviours of their peers as trained peer educators (PEs) and agents of behaviour change (Valente & Pumpuang, 2007). To engage OLs to promote the uptake of HIVST, 10 most frequently mentioned participants (MMCPs =5; FBWs = 5), were invited and trained to become PEs. Potential OLs were those whose advice or encouragement was sought by peers when making health decisions. A sample socio-metric method (Constenbader & Valente, 2003) was used to identify, select and recruit the OLs. The OLs had the advantage of being able to spend more time with their peers, who were likely to feel more comfortable with them in discussing a sensitive topic such as HIVST uptake.

The selected OLs attended two day training sessions conducted by BN, to become PEs. The training comprised of addressing the roles and responsibilities of the peer educator, routes of HIV transmission to alleviate HIV misconceptions, and skills on the appropriate use of oral-fluid HIVST kits including a 5-minute live video demonstration and simulation on how to use the kits. The content of HIVST kits uses include the importance of confirmatory blood-based HIV testing for all self-testers reporting reactive test results or prevention strategies such as VMMC or family planning for those reporting negative test results. Peer-educators also learned effective communication strategies (i.e. motivational interviewing technique), including how to counter negative viewpoints.

Also, skill building using participatory methods was a major component of the training. It involved role-playing delivery of the intervention sessions in Swahili (an official language in Tanzania), methods to engage peers in conversations about the BCI and how to improve PEs listening skills. The training allowed PEs to self-reflect and discusses with each other how to promote HIV self-testing, understand stigma and discrimination related to HIV testing and examine the benefits and barriers of using HIV self-test kits among peers. After attending a 2 full days of training sessions, PEs visited their peers through their respective social networks. During the visit, PEs informed their peers about the benefits of HIV testing and HIV self-testing in particular to create awareness about HIVST. At the end of the sensitization, PEs offered invitation cards to interested individuals and referred them to the study office within the study settings for eligibility assessment and enrollment. After enrolment, eligible participants were referred to the PEs to schedule attendance at the first intervention sessions.

The trained PEs provided the BCI to increase HIVST uptake and linkage to HIV prevention, care and treatment among their peers for a period of one month. PEs helped participants to moderate their negative feelings about fears of positive results, adverse effects of post HIVST testing and fear of seeing blood and/or needle pricks. For example, the use of oral HIVST tests was introduced as a measure to alleviate the fear of seeing blood or receiving a needle prick. PEs also informed peers about the benefits of HIVST, the importance of confirmatory testing after HIVST (i.e. those reporting a reactive result) and HIV prevention strategies (e.g. VMMC and family planning services). The PEs highlighted consequences related to not performing (e.g. being infected with HIV) or performing HIVST (e.g. fear of HIV positive results), the confidence of performing HIVST, and emphasized on significant others' (e.g. parents, peers, relatives, friends, etc.) approval of using HIVST.

The PEs used an educational strategy (i.e., adapted motivational interviewing (MI) technique) to deliver the BCI. Trained PEs carried out the sessions, which were approximately 45 to 60 minutes, in a simple and clear Swahili, to foster discussions and allow questions from participants rather than provide prescriptive, unequivocal and unidirectional information.

Acceptability of the intervention

The exit interviews revealed that overall, participants connected well with the peer-educators (PEs). The participants were comfortable interacting with the PEs because they considered them as friends. This was well elaborated by a FBW who said: *"The training was very helpful because our trainers [peer-educators] were just like our friends. We discussed the topics in a very friendly manner because we know each other…"* (FBW aged 28yrs old). Overall, most participants perceived the content and materials of the intervention positively, particularly the video show and demonstration on how to use HIVST. For example, a MCP said: *"All the materials were so helpful, although I liked the video and the demonstration most because I was able to see how to perform the self-testing and also practices on how to use the self-test kits"* (MCP aged 24 yrs. old). In addition, the use of the Swahili language during the training was perceived as very useful: *"…the instructions were in (Ki)Swahili, which was easy to understand very clearly…"* (FBW aged 20 yrs. old).

Participants described the use of picture cards very helpful in session facilitation of the BCI: *" This [self-testing instruction card], is a good one. These pictures are quite self-explanatory like people can look at it and understand what they can do"* (FBW aged 26 yrs. old). Also, participants noted that they were motivated to test for HIV using HIVST after attending the BCI. This is well described in the following narrative by a MCP who stated: *"When I came the first time for the training, I did not know that I would be offered self-testing. After the training I was motivated to use it [HIVST]…"* (MCP aged 27 yrs. old). Discussion on myths towards HIVST, motivational factors and benefits of HIVST increased their knowledge about HIVST, which was perceived as new 'technology' to most participants. As one respondent said: *"Previously, I knew that blood was used to test for HIV and now this new technology of using oral fluids? I wanted to perform HIVST using the self-test kit!"* (MCP aged 22 *yrs. old)*.

Participants experienced different levels of emotions while waiting for their HIVST test results. Some participants experienced anxiety, confusion and worry. For example, a FBW gave this narrative: *"I was anxious to know my test result. After collecting the oral fluid from my mouth and putting the brush [collecting device] in the small bottle with fluid [reagent] and waiting for 20 minutes,. I was looking at the display screen and saw a red colouration all over. I was confused…and asked myself ' what is happening now…?'…I continued watching until it started to clear after 10-15 minutes. I was relieved and waited until 20 minutes and I saw my result"* (FBW aged 24 yrs. old). In contrast, some participants were delighted and excited to see their HIV test results, particularly first-time testers: *"I was delighted to see my result after I performed self-testing for the first time in my life. It was a very exciting moment!"* (MCP aged 23 yrs. old). Participants perceived that the BCI was well planned and interesting: *"It was very interesting to participate in this project [BCI] and be able to test myself for HIV"* (MCP aged 28 yrs. old).

Feasibility of the intervention

At the end of the sessions, all participants rated their perceptions of intervention sessions and materials. Ratings for the overall intervention sessions ranged from 4.3 to 4.8 (max = 5). Overall rating on materials was between 4.7 and 4.8 (max= 5), as shown in Table 2.

Table 2: Participants ratings of perceptions on intervention sessions and materials

Items	Mean (SD)
Overall, intervention sessions… [a]	
had a clear structure	4.6(0.6)
taught me something new	4.6(0.6)
were well designed and complete	4.3(0.8)
were understandable	4.7(0.4)
were easy to follow	4.8(0.4)
were arranged in a consistent order	4.6(0.6)
were interesting	4.8(0.4)
were relevant	4.8(0.4)
were useful	4.8(0.4)
were helpful	4.8(0.4)

Overall, the materials presented in the intervention were… [a]	
Understandable	4.8(0.5)
Easy to use	4.8(0.5)
Presented in a consistent order	4.7(0.4)
Interesting	4.8(0.5)
Relevant	4.8(0.5)
Useful	4.7(0.4)
Helpful	4.7(0.4)

[a] Scale from 1 "I disagree" to 5 "I total agree "

Fidelity of implementation

The overall mean adherence score was 33.5 (SD 3.2) ranging from 28 to 38 (73 % to 100 %) out of a maximum score of 38. Six out of ten PEs scored above 33.5, indicating moderate adherence to the intervention content. Four of the PEs had scores below 33.5. Intervention components related to skills for HIVST use and perceived barriers/motivators were fully implemented, followed by myths around HIVST use and self - confidence towards HIVST uptake. The least implemented (partially or not implemented) intervention component was related to positive/negative consequences of HIVST uptake. The overall mean performance score was 15.5 (SD 1.9) ranging from 12 to 18 (66.7 % to 100%) out of a maximum score of 18. Seven out of ten PEs scored above 15.5 indicating the high performance of session facilitation. Three of the PEs had scores below 15.5. Session's facilitation techniques related to eliciting and answering questions and the use of reflective listening were fully implemented, followed by the presentation of session objectives, providing reassurance, reviewing the session objectives, checking to understand, building on participants' experiences and building general rapport. The least implemented (partially or not implemented) facilitation techniques were related to summarizing the sessions. The duration of session 1 varied from 40 to 60 minutes (max= 60 min). The overall mean session duration was 53 min (7.5) and 4 out of 10 PEs conducted session 1 below 53 min. The duration of session 2 varied from 40 to 45 minutes (max=45 min). The overall mean session duration was 42 min (2.6) and 6 out of 10 PEs conducted session 2 below 42 min (see Table 3).

Table 3: Peer educators adherence, performance scores and session duration (N=10)

Items	**Mean (SD)**
Adherence scores [a]	
Overall mean adherence scores	33.5(3.2)
Perceived barriers/motivators for HIVST	1.8(0.4)
Myths around HIVST	1.7(0.5)
Self-confidence towards HIVST uptake	1.7(0.5)
Positive/negative consequences of HIVST uptake	1.6(0.6)
Skills for HIVST use	1.9(0.3)
Performance scores [a]	
Overall mean performance scores	15.5(1.9)
Build general rapport	1.6(0.7)
Presentation of session objectives	1.8(0.4)
Building on participants experiences	1.7(0.7)
Provide reassurance	1.8(0.4)
Elicit and answer questions	1.9(0.3)
Use reflective listening	1.9(0.3)
Checking to understand	1.7(0.7)
Reviewing the session objectives	1.8(0.4)
Summarizing the sessions	1.3(0.5)
Session duration (in minutes)	
Session 1	53(7.5)
Session 2	42(2.6)

[a] scale from 0 "Not implemented" to 2 "Fully implemented"

Discussion

This paper describes the development of a systematic, theory-based BCI for FBWs and MMCPs to increase HIVST uptake and linkage to HIV prevention, care and treatment in northern Tanzania. The process included an extensive systematic review and evidence synthesis, formative research among key informants and the target population and the application of the PRECEDE-PROCEED planning model. In this study the PRECEDE -PROCEED model was the 'road map' that guided the whole process of planning, designing and developing the theory-based BCI (Green & Kreuter, 1999).

The strength of the BCI is based on the use of both theory and evidence. First, the components of the intervention addressed the identified key beliefs, facilitators/ and potential barriers that best explained the uptake of HIVST. Second, the alignment process helped to tailor the components of the intervention to suit the social context of the local setting. The systematic use of the BCTs approach assisted in the selection of intervention functions and specific BCTs from the BCCTv1 (Abraham & Michie, 2008; Michie et al., 2013). The selection of the relevant BCTs and intervention functions helped to initiate behavioural change more logically and transparently.

The intervention that was developed built upon behavioral change theory, but required adaptation and tailoring to the context-specific needs of the target population. One notable adaptation was the importance of using the existing social networks of the targeted population, particularly MMCPs, as an effective strategy to promote awareness for HIVST uptake (Njau et al., 2020).

The content of using existing social networks helped peers to create safety nets within which to discuss issues affecting their own health, including HIV testing, and engage in HIV testing conversations. Existing evidence suggests an association between willingness to self-test for HIV among men and HIV testing conversations with a close friend (Njau et al., 2020). The local CAB recommended the use and nomination process of 'opinion leaders' who were trained to be PEs to provide the proposed BCI, to their peers. The stakeholders also suggested the key roles and responsibilities of the trained PEs.

The suggested roles and responsibilities helped PEs to provide correct information and make proper follow-up of trainees, maintaining the confidentiality of trainees' information and showing respect to fellow PEs and trainees. Existing evidence suggests that PEs have a positive effect on HIVST uptake, because of the possibility of decreasing HIV-related stigma among peers (Valente & Pumpuang, 2007). The second modification of the intervention was the use of an effective communication channel based upon an educational strategy, the MI technique. Results from the formative research (Njau et al., 2020), and inputs from the stakeholders meeting highlighted that awareness creation, advocacy, and intervention promotion would be possible through effective communication channels.

The MI technique is built upon Prochaska's stage of change, which suggests that behavioural change is a complex and cyclical process, involving interactions between physical dependence, social factors and motivation (Prochaska et al., 1994). Globally, existing evidence supports the effectiveness of the MI technique in interventions for behavior change (Aarø et al., 2016; Corbie-Smith et al., 2010; Mkumbo et al., 2009; Theunissen et al., 2013; van Empelen et al., 2003; Wolfers et al., 2012; Wolfers et al., 2007).

The PEs were trained on the basic principles of the MI technique to stimulate intrinsic motivation (e.g. decision to test for HIV) of the study participants. The content on intrinsic motivation helped peers to understand their decision-making process to test for HIV, and underlined the importance of the inherent satisfaction rather than external pressures or rewards to motivate decision making for testing for HIV (Prochaska et al., 1994). Further, PEs were asked to encourage participants to explore their uncertainty about HIVST and their readiness to change. The content on uncertainty about HIVST and their readiness to change enabled peers to comprehend the benefits of HIVST and move through the process of behavior change for HIVST uptake (Prochaska et al., 1994).

Also, PEs were trained to create a good rapport by avoiding arguments, discussing stigmatized behaviours, expressing empathy (i.e. acceptance of the participant's knowledge, attitudes and experiences of HIV testing), and acknowledging participants' autonomy in deciding to test for, or not to test for HIV.

The content on autonomy help the participants to take stock of their decision-making process for HIVST uptake for HIV testing by allowing them to dictate the terms on which they test their HIV status. Also, autonomy created the sense of self-empowerment for participants to take responsibility of one's life is a potential facilitator for HIVST uptake (Njau et al., 2019). Finally, although initially a group intervention approach was deemed feasible, we decided on an individual model. The local CAB suggested that the group model would restrict participants to fully share their HIV testing experiences and/or fears related with HIV testing.

Acceptability of the intervention

The present results suggest that the BCI is acceptable to hard-to-reach people in an urban setting in northern Tanzania. Most study participants perceived the use of trained peer-educators who were selected among study participants very helpful. This observation may explain the high levels of acceptability reported in the current study. Systematic review evidence suggests that peer-led interventions are associated with high acceptability of HIV prevention, including increasing HIV knowledge, HIV prevention among injection drug uses and condom use (Medley et al., 2009).

The acceptability of peer-education interventions is related to the strong influence that peers have on individual behaviour and the level of trust and comfort with their peers that allows for more open discussions of sensitive topics (Chanda et al., 2017; Ford et al., 2008; Geibel et al., 2012; Oldenburg et al., 2017; Onyango et al., 2016).

Study participants accepted the content, materials and procedures used in the BCI. This was indicated by high ratings from participants' feedback. The helpfulness of specific materials was reported, particularly for the video show. Also, participants appreciated the use of Swahili as the medium for instruction during training. In addition, participants mentioned the use of pictorials was very helpful. Previous studies have reported the use of a clear, well-understood language and the use of visual aids and pictorial images help in increased identification with the information and messaging (Figueroa et al., 2015; Ng et al., 2012; Ortblad, Chanda, et al., 2018; Ortblad, Kibuuka Musoke, et al., 2018). Discussion on misconceptions about HIVST helped participants to regulate their negative feelings about HIVST. This helped to provide insight into the perception of HIVST as a new 'technology'. From the theoretical perspective, regulating negative emotions related to behaviour is fundamental in the behaviour change process (Tavender et al., 2015).

Fidelity of implementation

Evidence for the fidelity of implementation varied for adherence and performance scores of trained PEs. The study findings indicate a moderate level of fidelity of adherence to the specified BCTs and a high level of fidelity of performance of session facilitation. These findings suggest that trained PEs implemented most BCTs and session facilitation skills fully. Other contributing factors for the fidelity of implementation include the optimal length of training sessions and successful recruitment and retention rates in this study.

Conclusion

The present findings suggest the BCI was well acceptable, and feasible among hard to reach populations in an urban setting in northern Tanzania. Moderate level of fidelity of adherence to the specified BCTs and high level of fidelity of performance of session's facilitation was noted. To the author's knowledge, this is the first BCI for increasing HIVST uptake, linkage to HIV prevention, care and treatment that is built on theory and informed by local CAB inputs in northern Tanzania.

Strength and limitations

The strength of this study is the use of PRECEDE-PROCEED model known for guiding the planning, designing and development of BCIs. Another strength is the adaptation of the COM-B framework and the BCW used through the selection process of intervention components. The process provided a deeper understanding and insight into the relevant intervention components, which assisted the

development of a tailored, theory-based BCI. A potential methodological limitation of this study could be the influence of how the research team operationalized the theoretical domains in terms of appropriate intervention components. For this intervention, only one research team conducted the systematic and replicable process, which is a limitation.

Ethics consideration

Ethical approval was obtained from the Kilimanjaro Christian Medical University College Ethics Committee (CREC: 884; dated: 6/1/2016), the National Institute of Medical Research in Tanzania (NIMRIHQIR.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 Drugs Authority (TFDA) approved the Oral HIV kits. All eligible participants provide written consent. Participants were aware of their voluntariness to participate and freedom to withdraw at any point from the research.

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Competing interests

The authors declare that they have no competing interests.

Authors' contributions

BN is the guarantor. All authors contributed to the conception and design of this manuscript as follows. BN and CM conceived the intervention. BN, EL and DD designed and developed the intervention under the supervision of DM and CM. BN wrote the manuscript under the supervision of DM and CM. All authors read the final draft of the manuscript and provided feedback. All authors read and approved the final manuscript.

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