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Original Article

Mobile health-delivered narrative intervention to increase cervical cancer screening among Malawian women living with HIV: A pilot randomized controlled trial



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ABSTRACT

and VIA uptakes.

Objective: This study aimed to develop and evaluate a mobile health (mHealth)-delivered, theory-guided, culturally tailored storytelling narrative (STN) intervention to increase cervical cancer screening among Malawian women living with human immunodeficiency virus (HIV).

Methods: This study involved two phases: Phase 1: development of a theory-guided and culturally adapted STN intervention and Phase 2: a pilot randomized controlled trial was conducted. Participants were randomly assigned to one of three arms: Arm 1: tablet-based video (mHealth) with STN (n=60); Arm 2: mHealth with a video of nonnarrative educational materials (n=59); and Arm 3: control group with only reading nonnarrative educational materials in person (n=60). Cervical cancer screening was measured using visual inspection with acetic acid (VIA) uptakes by self-report and health passport record review at 2 and 6 months after intervention. *Results*: Both arms 1 and 2 had nearly twice the rate of VIA uptakes than those in Arm 3 (51.0% and 50.0%, respectively, vs. 35.0%, P=0.01) at 2 months follow-up, but there were no differences among groups from 2- to 6-month follow-ups. All groups demonstrated significant improvement of knowledge about risk factors, intention,

Conclusions: The findings demonstrate the preliminary effectiveness of the intervention on cervical cancer screening behavior and the feasibility of the study regarding recruitment, retention, treatment fidelity, and acceptability of the single 30-min session. The feasibility and the preliminary results of the effectiveness of the proposed study indicate scaling up the STN intervention to a larger population of women to increase cervical cancer screening uptake to prevent deaths due to cervical cancer in Malawi.

Introduction

Low- and middle-income countries (LMICs) now face a double burden of confronting both communicable diseases and non-communicable diseases (NCDs).^{1,2} Almost three quarters of NCD deaths worldwide occur in these countries.^{2,3} Cervical cancer (CC) is

the fourth most common cancer among women, and approximately 90% of CC cases occur in LMICs.⁴ Malawi has the highest rate of CC (75.9 per 100,000) in the world, and more than 80% of Malawian women diagnosed with CC are at the inoperable cancer stage.^{5,6} Precancerous changes of the cervix, virtually all of which are caused by chronic infection with the human papillomavirus (HPV), can be

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detected during screening and treated to prevent the development of invasive CC.

Women living with human immunodeficiency virus (WLWHIV) are more likely to have persistent HPV infection leading to cervical abnormalities and CC. In Malawi, over 8% (or 946,000) of the adult population are chronically infected with HIV, and CC is an acquired immune deficiency (AID)-defining illness, and WLWHIV are 3–8 times more likely to develop invasive CC than women who are not HIV infected. ^{4,7} This double epidemiologic burden will continue to increase unless significant efforts are made to prevent and control CC, a preventable and curable cancer when detected early.

The World Health Organization (WHO) promotes visual inspection with acetic acid (VIA) and treatment with cryotherapy (local freezing of a suspicious lesion of the cervix) as an affordable and adaptable method for detection and treatment of precancerous cervical changes in lowresource settings.⁸ However, data indicated that the screening for CC was only at 10% in Sub-Saharan Africa, which is far below 70% of the targeted cervical cancer screening (CCS) of the WHO. 8-10 Screening rates for CC in Malawian women with or without HIV are extremely low—only 26.5%. 11 Cancer screening has not been seen as a priority for healthcare services in Sub-Saharan Africa including Malawi due to the overwhelming burden of communicable disease and infection-related high mortality. 12 Moreover, the cancer management infrastructure including chemo-and radiation-treatment is scarce in Malawi, so if WLWHIV do not detect their CC early, they are highly unlikely to get cancer treatment. Prevention of HPV-related CC in HIV-infected individuals, particularly in the context of resource-constrained settings, where prevention-oriented services are either lacking or the health beliefs of the population are oriented toward the treatment of infectious diseases, is problematic. A systemic literature review of CCS uptake in low-income countries reported there was a wide range of barriers including education, knowledge, awareness, attitude, health belief, stigma, accessibility to CCS sites, etc. 13,14 The findings from Malawian women showed similar findings to women from Sub-Saharan Africa such as individual levels of knowledge, misunderstandings, attitudes, sociocultural factors of geographic distance and access to the VIA clinics, etc. 15,16

Health education is essential to promote CCS. A variety of health education interventions have been tested including calls, mailed postcards, consultations, picture books, tablet-based, videos, lecture presentation, tailored counseling, etc. consistently reported the impact of health education interventions on improving knowledge, awareness, and attitude, but significant changes in CCS uptake were not reported. ^{17,18} These findings point out that knowledge alone is not sufficient to change health behavior. 19 Studies that focus on health-seeking behavior revealed that individuals use health services not only because of an individual's perception of need and own choice (autonomy) but also due to external social influences including suggestions, cajoling, nagging, and pressure of others as well as recommendations by a physician. 15,20 Moreover, Malawian women have low literacy not only in their own indigenous language (Chichewa) but also in English. They not only face the challenges of accessing infectious disease management but also have limited knowledge to support their follow-through on preventive behavior. Given the low level of knowledge about CC screen to draw upon, promoting CC screen health behavior requires innovative and situation-specific approaches. Culturally tailored and evidence-based interventions to increase screening uptake are imperative.

The oral storytelling traditions of Africa have long been recognized around the world as a powerful tool for communication, $^{20-22}$ but oral storytelling has not been tested to examine its impact on promotion of CCS among Malawians. There is a need to design engaging, effective, culturally tailored, and evidence-based studies to promote CCS, particularly in community under-represented and understudied for technology-based intervention, such as Malawian women living with HIV in rural areas. Narrative theory posits that culturally grounded, high-quality logical storytelling affects an audience's attitude and behavior through the interaction of transportation and identification, $^{20-24}$ factors known to support the efficacy of

narrative, culture-centric health promotion interventions. ^{25,26} Storytelling narrative (STN)-based interventions with messages urging CCS from healthcare professionals and other WLWHIV is proposed as a means to engage low-literacy populations in health behavior changes such as increasing the uptake of cancer screenings. The combination of the oral storytelling traditions of Africa and the known culturally grounded impact of content drawn from within a population to be addressed with health promotion messages drove our decision to develop and test a storytelling-based intervention for this specific purpose of promoting CCS for rural Malawian women.

The effectiveness of storytelling in changing attitudes and behaviors follows from its ability to break down cognitive resistance through identification and emotional connection with characters in the narrative, thus enhancing the viewer's or listener's acceptance of the values and beliefs portrayed in the storyline. $^{20,27-29}$ The conceptual basis for the influence of stories on behavior derives from perceived realism, identification, and transportation. $^{20,22-24,29,30}$

In addition, narrative interventions made available in the new social media landscape hold the promise of engaging people in more active participation in health self-management. ^{20,22,31} The rapid penetration of mobile phones across low-resource countries including Malawi²⁶ has raised hopes regarding leveraging mobile health (mHealth) technology to deliver healthcare interventions to improve CC screen. mHealth in general refers to the use of mobile devices and other wireless technology in health care and health research. 32,33 Though there has been a rapid increase in the use of phones in Malawi, the affordability of Wi-Fi and access to electricity is low as access to fixed-line telecommunications has been limited.³⁴ Mobile connection in Malawi is at 57.2%, but many people make use of more than one mobile connection.³⁵ Phone access is unevenly distributed between and within the country, and it is seldom affordable and reliable with low-income groups, women, and rural populations who are disproportionately excluded in poor countries. 36,37 A recent WHO guideline urges to create innovation and technology to reduce the inequities and provide greater mHealth usability equally.³⁸ We are in line with the WHO position that phone access limitations should not hamper the benefits of utilizing mHealth for underserved populations but rather provide greater mHealth usability for these unfortunate populations. To address these limitations, we developed novel strategies to use an unsynchronized computer-assisted personal interview by using battery-charged tablets to collect data in the field and synchronize the data at a research office at the university, wheresteady electricity and Wi-Fi are available.

The purposes of our study were (1) to develop a theory-guided and culturally grounded STN intervention and novel strategies using unsynchronized mHealth delivery and (2) to conduct a pilot randomized controlled trial (RCT) to examine the preliminary effectiveness of narrative interventions on CC screen prevention as well as to examine the feasibility of recruitment, randomization, and intervention and implementation. The milestones listed in the following will be used to estimate important parameters to assess the feasibility of proceeding to a large-scale trial:

- 90% of HIV support groups agree to participate in the study.
- 90% of those who agree with the study show up at the research site.
- 90% of participants accept their random assignment.
- 90% of participants watch the entire STN-video interventions on tablets.
- 90% of participants return for post-2-month observation.
- 90% of participants who complete post-2-month observation return on post-6-month observation.

Methods

This study involved two phases: Phase 1: development of a theoryguided and culturally adapted STN intervention and Phase 2: the delivery of the intervention on mHealth by asynchronized battery-charged tablets to deliver interventions and data collection in the field and to synchronize the data at the research office where steady electricity and

Wi-Fi are availabe. There are two intervention groups (Arm 1: an intervention group of a STN video on tablets i.e., mHealth delivered] and Arm 2: a comparison group of a video with a voice-over presenting didactic materials on tablets i.e., also mHealth delivered]). To detect the different components of the interventions of a combination of STN and mHealth versus only mHealth, a comparison group in Arm 2 only watched videos of a Malawian research assistant reading the nonnarrative educational materials, which are the same materials used in Arm 3. This study was approved by the institutional review board of a university in the Northeast United States and a university in Malawi.

Settings

This research project was conducted in collaboration with HIV support-group communities and community health leaders. This research project was situated in Lilongwe, the capital city, and implemented within the Malawi health system. In Malawi, healthcare services are provided by both public and private sectors. Lilongwe is a district in the central region of Malawi. The district covers an area of 6159 square kilometers and has a population of 1,346,360.³⁹ Three quarters of all communities in the Lilongwe district are at least 10 km from the city and meet the national definition of rural areas. The public sector includes all facilities under the Ministry of Health, which provides services free of charge at the point-of-service delivery. The private sector consists of private for-profit and private not-for-profit providers, mainly the Christian Health Association of Malawi, which provides both services to patients and trains health workers.⁴⁰

Although Malawi has CC screen programs that are either administered by the government or nongovernmental organizations, these programs generally fail to reach a significant majority of women. The delivery of CC screen and early treatment is compromised due to a shortage of healthcare professionals, lack of equipment and supplies, as well as the long distance to health facilities and bad road conditions. As for WLWHIV, the Malawian government recently provided a structured approach to CC screen within HIV clinics so that those women who regularly attend an HIV clinic can have more access to VIA uptakes and other healthcare than women without HIV. However, though CC screen within an HIV clinic is a logical strategy and is important; it has been implemented in a limited number of clinics with available funds and is mainly accessible to WLWHIV in urban settings.

Phase 1: Narrative intervention development

Story content

A situation-specific theory was used to conceptualize how people come to decide about and act on health behavior changes including CC screen uptakes. ^{15,16} Utilizing a within-culture point of view, we

developed STN videos drawn from qualitative studies with Malawian women and a series of interviews with Malawian WLWHIV and community health leaders. The proposed theoretical framework (Fig. 1) acknowledges that effective health education is located at the intersection of knowledge and the attitude of the individual, social networks, community, and social factors.

The STN intervention development was based on the successful development of the STN videos in our previous studies using the theoretical framework described.^{20,41} We identified and selected "Star" storytellers whose stories reflect CC screen behavior among Malawian WLWHIV and developed customized interview guides for the videotaping of each star. The content of STN videos were focused on a series of health messages based on the situation-specific theory, narrative communication, the cultural background of participants, and the desired behavior change, as shown in Fig. 1. We selected "Star" storytellers with particularly salient stories and asked them structured questions based on the proposed integrated theory to provide concrete illustrations of the theoretical concepts (variables). Storytellers were invited to discuss their own experiences and how they were influenced by suggestion, nagging, or pressure from their social network members in their decision to undergo CCS and how they dealt with the barriers presented by CCS within the broader context of the Malawi women living with HIV (MWLHIV) patient's life. The STN was developed as first-person narratives based on real stories from Malawian WLWHIV. Storytellers share their stories or experiences related to CCS including suggestions, nagging, and pressure from their family, friends, and healthcare workers in their own words and in their language (Chichewa). Also, they discussed how they dealt with the barriers presented by CCS within the context of WLWHIV. Additional supporting materials, including a "Learn-More" video to present clinical information about CC screen among WLWHIV, were developed.

We worked closely with Malawian community advisory board (CAB) to develop the STN intervention reflecting Malawi sociocultural context. Multiple rounds of recordings were made until a full elaboration of their salient stories was captured. 20,42 CAB members and research teams independently reviewed the videos multiple times and rated storylines for their links with key concepts in conceptual frameworks and cultural and literal sensitivity as well as emotional engagement. One of the community leader reviewers stated that "I cannot move on watching next video clips." She continued, "Now I found out that my mom died from CC though it could be prevented and treated, and if I would know this information earlier, I could not let my mom die." She suggested giving the viewers some break time to think and work on emotional intensity. The HIV support-group leader reviewers rated most highly the interactive process of delivering knowledge about CC and CC screen as storytellers presented incorrect messages, but later, this misinformation was corrected by physicians in the Learn-More section. The support-group leaders stated that stories are very real because these captured the issues

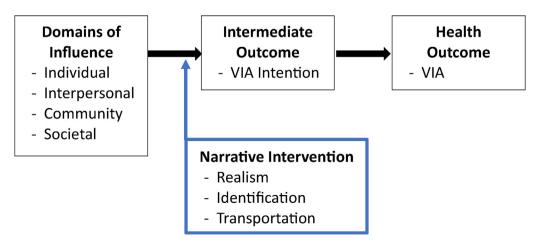


Fig. 1. Integration of situation specific theory and narrative communication theory.

of misunderstanding about CC and CC screen among Malawian women yet clarified the misunderstandings with facts as an engaging teaching method. We used images and drawings in stories to ensure effective health and cultural communication that the participants would understand medical information as well as easily relate to themselves. The most highly rated storylines were woven into a series of videos. The STN contained three video clips taking roughly 25 min of time and 8 min of the Learn-More video. Also, based on the reviewers' suggestions, we added a 5-min intermission time between three stories and the Learn-More section. The stories in Chichewa were translated into English and captioned at the bottom of the screen. The Learn-More video was dubbed into Chichewa and captioned in English.

Phase 2: Implementation of RCT

Study population

The study was conducted among Malawian WLWHIV whose members of HIV support-groups were in the Lilongwe district. The district HIV

prevalence rate is 9.2%, and it has many HIV support organizations such as the National Association of People Living with HIV/AIDs in Malawi that are membership organizations and exist in all districts of Malawi. Members join of their own free will and form support groups within their communities. The support groups are established to fight stigma and discrimination, advocate for supportive environments for people living with HIV, and facilitate local support.

Sample size and inclusion criteria

Since this is a pilot study that aims to evaluate feasibility rather than hypothesis testing, sample size calculation was not conducted. A total of 180 (60 per arm, three arms in total) was the target sample size based on an assumption that approximately 80% participants would complete the whole study procedure.

Women were eligible for participation if they were (1) confirmed HIV-positive, based on medical record, (2) HIV-support-group members, (3) female aged 20–50 years, (4) had no prior CC screen, (5) had no history of invasive CC, and (6) had the willingness to participate in the

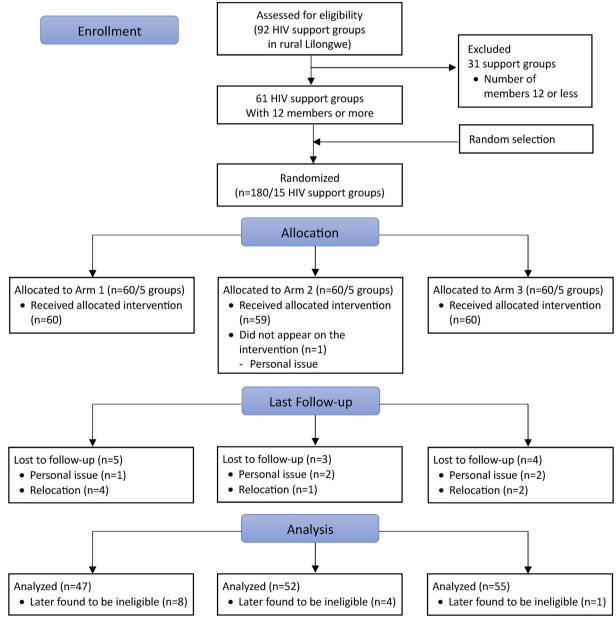


Fig. 2. A pilot RCT profile: Flow of participants. RCT, randomised controlled trial.

study. We limited the age range to 20–50 years for CC screen based on WHO or Malawi government guidelines for WLWHIV. 8

Recruitment

We closely worked with both public officers of the District Council and HIV-support-group leaders for recruitment of support groups as well as individual participants within the selected support groups. The District Council has over 1600 support groups, and it has a defined governance structure with a board of trustees. Each support group has a leader who is also living with the HIV condition. Support-group leaders are open about their HIV infection to help their group members to identify with them and to increase their level of trust in them. They also serve to educate others as client (patient) experts. Leaders schedule meetings and serve as peer mentors and act as liaisons with the offices of the District Council and other nongovernmental organization groups. To recruit and retain the participants, multiple strategies were utilized including (1) research activities being conducted in their community sites due to problems with rural transportation; (2) pay incentives being given to each participant with completion of each subsequent activity as they moved through the steps of the study; and (3) HIV-supportgroup leaders were recruited as data collectors and trained, but they were blind for group assignment until arrival at the site. All research team members had experience working with the study population and had been involved in several research studies focusing on health and health behavior. Monetary compensation was offered for participation in the study for both the control and intervention group members to encourage participants in the mHealth program using a staged manner. Pay incentives were given to each participant with completion of each subsequent activity, with payment of \$5, \$2, and \$3 as they moved through the steps of the study, based on our past experiences and a recommendation from CAB.

Randomization and masking

This study used a random-cluster sampling method. Fig. 2 shows the flow of participants using the Consolidated Standards of Reporting Trials statement flowchart. 43 Local HIV support groups were the primary sampling unit. HIV support groups were eligible if they had 12 or more active group members in September 2021. We were able to engage 61 HIV support groups that were active, located in rural areas, had 12 or more members, and their group leaders expressed interest in this study. From the 61 HIV support groups, 15 support groups were randomly selected, and then the random assignment was performed by using a computerized randomization system generated by the program manager. The distance between the intervention and control arms needed to be at least 4 km to avoid potential contamination. Once the schedule for intervention implementation was confirmed for each group, the program manager informed the intervention type of the group to Malawian co-investigator who recruited the participants, and the information was shared with data collectors just before the baseline data collection to avoid detection bias.

Although English is the official language of Malawi, a large majority of Malawians speak Chichewa, with only a small number speaking English outside the urban areas. While we provided consent forms in both English and Chichewa, all participants chose Chichewa for the informed

consent and health survey. A thumb impression was obtained as signature proxy from participants who were illiterate. The participants were assured that all information would be kept strictly confidential, and a code was assigned to the interviews to anonymize them. Data were stored on a secure server protected by a password, with access restricted to study researchers.

Intervention condition

The intervention was STN videos and mHealth (Fig. 3). Participants watched a single session of 30 min at the community centers. Regarding mHealth, we developed novel strategies to overcome limited Wi-Fi access and unstable electricity by using battery-charged tablets to show intervention video clips. These strategies to support the limited technology were also used to collect data in the field and synchronize the data at a research office at the Malawian subcontract site, where steady electricity and Wi-Fi were available.

Intervention-Arm-2 participants watched a tablet-based video that captured a Malawian research assistant reading didactic material based on WHO and Malawian public health guidelines (no storytelling) for 20 min. The participants in the control group listened to didactic materials the same as in Arm 2, but research assistants read the information inperson for 20 min instead of watching on the tablet. No handout material was provided to all groups. The research assistants in Arms 1, 2, and 3 all received tablets at the beginning of the study along with technical assistance.

Research assistant training

We recruited bilingual HIV-support-group leaders as data collectors and held 3-day training workshops (1) to introduce the aims and methods of the study; (2) to train them on the use of a tablet computer; (3) to host a mock data collection section with pairs of data collectors to interview each other and practice data collection with a tablet computer; and (4) to hold the training sessions until data collectors felt confident enough to initiate data collection.

Data collection

Knowledge, VIA intentions, and uptake assessments occurred at baseline (Observation 1), and immediately following the intervention (Observation 2) as well as at 2 (Observation 3) and 6 months post the baseline (Observation 4) by using computer-assisted person interviews. Tablet-based data collection methods were used by the bilingual Malawian data collectors who read the survey and marked the answers on the tablet on behalf of the participants.

Measures

Socio-demographic characteristics were assessed at the baseline including age, marital status, education, income, and religion. The primary outcome was VIA uptake, and secondary outcomes were changes in knowledge and intention of VIA uptakes.

VIA uptake

The CC screen measured with VIA uptake was assessed through selfreporting and the review of Malawi's health passport at Observations 3

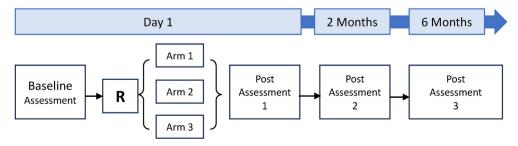


Fig. 3. Overview of a pilot RCT process. RCT, randomised controlled trial.

and 4. ^{15,44} The Malawi health passport is a portable abridged medical record belonging to the patient. Women are expected to carry a health passport (a patient's medical record) with them when they use healthcare services.

VIA intention

Intention of receiving CC screen was measured at Observations 2–4. It was measured with the question "Have you ever thought about receiving VIA?" with three options of yes, no, or I do not know. The skip pattern was applied based on the participant's self-reports of VIA uptakes at Observations 3 and 4.

Knowledge

Items assessed knowledge about CC screen, and perceived risk for CC were derived from literature review of the studies conducted in Malawi and other Sub-Saharan African countries as well as existing tools 15,45 and assessed self-reporting at the baseline and Observations 2–4. The collected items were translated into Chichewa with a WHO forward translation, 44 and then cognitive interviews were conducted with 10 Malawian WLWHIV to improve its clarity and assess respondents' ability to comprehend what was being asked and read with fluency with a natural flow in Chichewa. The final items consisted of 11 items for CC screen and 13 items for perceived risk for CC that can be answered with yes, no, or do not know. The potential score range was 0–24 with a higher score indicating better knowledge. The reliability for CC screen subscale (11 items) was Cronbach's $\alpha=0.83$ and risk factor for CC (13 items) was $\alpha=0.78$.

Feasibility and acceptability measures

Recruitment and retention were assessed among participants at three points: the baseline and 2- and 6-month follow-ups. Recruitment rates were calculated from the number of support groups approached and nonparticipation. The flow of recruitment and follow-up in the study is shown in Fig. 1. The field notes focusing on issues related to recruitment by the Malawian research team, HIV-support-group leaders, CAB members, and interviewers were gathered. Also, we interviewed CAB members, HIV-support-group leaders, and WLWHIV to assess their perception of mHealth technology and STN and the dosage of interventions.

Also, cognitive interviews were carried out with 10 WLWHIV who were selected from HIV support groups using a purposeful sampling strategy. Participants in the cognitive interview were excluded from the pilot RCT. After watching storytelling videos, cognitive interviews were conducted in person to assess their perception of mHealth technology and storytelling videos, and the dosage of intervention. Interviewers also asked questions about their feelings or emotional engagement such as whether they were tired, bored, or emotionally engaged while watching the videos (details of the findings of measures of the ST narrative intervention will be published in a different manuscript).

Sample size

We based our sample size on accepted practice for pilot studies and practical consideration. ⁴⁶ We aimed to recruit 180 participants for our feasibility measures and to generate a preliminary estimate of effect for the intervention.

Data analysis

To obtain effect-size estimation for future larger intervention studies, we assessed the distribution and variability of the data, including changes over time in CC screen uptakes as well as the levels of knowledge about risk factors and CC.

While not designed to provide definite evidence of a meaningful treatment effect, preliminary efficacy analyses were performed. A global test of three arms was performed using Analysis of Variance (ANOVA) to compare differences in knowledge. χ^2 test was used to compare CC screen uptake across intervention groups. Then, post-hoc pairwise comparisons were conducted to explore any significant difference between the two arms (Arm 1 and Arm 2). McNemar's test and paired t test were used to examine within-group changes. All efficacy endpoints were compared based on prespecified hypotheses. Significance was taken at P < 0.05. All analyses were performed by intention-to-treat.

Ethical considerations

This study was approved by the institutional review board of a university in the Northeast United States (IRB No. 2019250) and a university in Malawi (IRB No. P.04/2021/011). Protocols were observed from all the participants before interacting with them as they were preinformed and had signed an informed consent form before data collection. Regarding the process of obtaining informed consent, although English is the official language of Malawi, a large majority of Malawians speak Chichewa, with only a small number speaking English outside the urban areas. Therefore, we provided consent forms both in English and Chichewa. A thumb impression was obtained from participants who were illiterate. The participants were assured that all information would be kept strictly confidential, and a code was assigned to the interviews in order to anonymize them. Data were stored on a secure server protected by a password with access restricted to study researchers.

Results

Demographic characteristics

Demographic and descriptive characteristics of 179 Malawian WLWHIV participants allocated to each group are summarized in Table 1. At the baseline, participants in the intervention groups did not differ significantly from participants in the control group regarding their demographic data except fewer women in Arm 2 reported currently being married than those in Arm 1 and Arm 3 (39.0% vs. 61.7% and 60.0%, P=0.028). Most participants were aged 40 to 50 years, were Christian, were currently married, and had completed primary school. Most participants reported that their health status is very good or good and that they received their HIV diagnosis less than 10 years ago. Sixty-nine percent of all randomized participants had ever thought about receiving CC screen before the intervention. All selected the Chichewa language for the study.

Feasibility and acceptability

Feasibility

Feasibility was measured by recruitment, randomization, and retention rate. Of the 180 eligible participants from 15 selected HIV support groups (n = 180), only one intervention participant missed the study, though the eligible participant informed the recruiter that she was not able to participate due to an unexpected family funeral service. All participants were randomized into three arms successfully, and there was a 0% dropout rate after randomization, which exceeded 90% of benchmarks set, so measures show the feasibility of recruitment and randomization. The retention rates were 95.5% (171/179) and 93.3% (167/179) at 2 months and 6 months, respectively, and there was no difference between intervention and control groups. The dropout was due to participants' relocation, funeral attendance, and sickness. However, we found that those 25 participants had a history of having received a VIA screening before enrollment when we checked medical passports to cross-check self-reported CC screen uptakes at 2 months after observation. We learned that they confused a VIA with pelvic examinations or a woman's examination. These 25 participants with a history of CC screen

 Table 1

 Sociodemographic characteristics of participants.

Characteristics	Total	Arm 1	Arm 2	Arm 3	P value ^a
	n = 179	<i>n</i> = 60	n = 59	n = 60	
Age					
20-29 years	13 (7.3)	3 (5.0)	1 (1.7)	9 (15.0)	0.1
30-39 years	43 (24.0)	15 (25.0)	15 (25.4)	13 (21.7)	
40-50 years	123 (68.7)	42 (70.0)	43 (72.9)	38 (63.3)	
Religion					
Christian	161 (89.9)	56 (93.3)	52 (88.1)	53 (88.3)	0.58
Others	18 (10.1)	4 (6.7)	7 (11.9)	7 (11.7)	
Marital status					
Never married	1 (0.6)	1 (1.7)	0 (0)	0 (0)	0.028
Married	96 (53.6)	37 (61.7)	23 (39.0)	36 (60.0)	
Divorced	30 (16.8)	11 (18.3)	10 (16.9)	9 (15.0)	
Widowed	52 (29.1)	11 (18.3)	26 (44.1)	15 (25.0)	
Education					
Never attended school	65 (36.3)	20 (33.3)	24 (40.7)	21 (35.0)	0.94
Primary school	99 (55.3)	35 (58.3)	30 (50.8)	34 (56.7)	
Secondary school	15 (8.4)	5 (8.3)	5 (8.5)	5 (8.3)	
Language at home					
Chichewa	179 (100.0)	60 (100.0)	59 (100.0)	60 (100.0)	NA
Literacy					
Can read Chichewa	96 (53.6)	33 (55.0)	29 (49.2)	34 (56.7)	0.69
Can write Chichewa	92 (51.4)	31 (51.7)	27 (45.8)	34 (56.7)	0.49
Had any income in 1 year	104 (58.1)	39 (65.0)	32 (54.2)	33 (55.0)	0.41
Monthly household income	,			,	
< bK 50,000	121 (67.6)	41 (68.3)	39 (66.1)	41 (68.3)	0.9
K 50,000	23 (12.8)	6 (10.0)	8 (13.6)	9 (15.0)	
Do not know/not sure	35 (19.6)	13 (21.7)	12 (20.3)	10 (16.7)	
Self-rated general health			,,		
Very good	18 (10.1)	10 (16.7)	4 (6.8)	4 (6.7)	0.08
Good	81 (45.3)	19 (31.7)	24 (40.7)	38 (63.3)	
Moderate	60 (33.5)	22 (36.7)	23 (39.0)	15 (25.0)	
Bad	8 (4.5)	3 (5.0)	4 (6.8)	1 (1.7)	
Very bad	12 (6.7)	6 (10.0)	4 (6.8)	2 (3.3)	
HIV diagnosis	(*)	2 (2012)	. (515)	_ (0.0)	
Less than 10 years ago	113 (63.1)	38 (63.3)	31 (52.5)	44 (73.3)	0.18
More than 10 years ago	57 (31.8)	20 (33.3)	23 (39.0)	14 (23.3)	0.10
Don't know	9 (5.0)	2 (3.3)	5 (8.5)	2 (3.3)	
Reproductive health	5 (6.0)	2 (8.8)	0 (0.0)	2 (6.6)	
Age at first period, year	14.12 (1.73)	13.93 (1.6)	14.12 (1.64)	14.32 (1.94)	0.48
Number of pregnancies	5.64 (2.4)	5.75 (2.3)	5.59 (2.4)	5.58 (2.4)	0.91
Ever used oral contraceptives	62 (34.6)	21 (35.0)	18 (30.5)	23 (38.3)	0.67
Had abnormal vaginal discharges	21 (11.7)	10 (16.7)	7 (11.9)	37 (61.7)	0.24
Had abnormal vaginal bleeding	11 (6.1)	7 (11.7)	2 (3.4)	2 (3.3)	0.12
Have ever thought about receiving CCS	123 (68.7)	46 (76.7)	38 (64.4)	39 (65.0)	0.12

Data are n () or mean (standard deviation).

CCS, cervical cancer screening; NA, not applicable; HIV, human immunodeficiency virus.

were excluded from the final data analysis. Participants expressed that ethnicity and language matched stories from local community members for the videos were Malawian-specific and easy to identify with them.

Acceptability

CAB members provided iterative feedback on intervention materials that increased the likelihood that STN interventions were culturally relevant. Also, we presented our preliminary findings to the Malawian community of selected study participants and community health leaders including physicians, nurses, HIV-support-group leaders, and public health officers. All participants and data collectors who were HIV-support-group leaders indicated that the length of the video was acceptable except for one participant by stating that the videos were too long to the extent that participants were getting tired. One of the data collectors stated that "the storytelling video was very powerful, and participants were listening attentively compared to other videos and reading the script" and asked, "why did we not show all the participants the storytelling videos?" Most Malawian community leaders all strongly supported and asked for consideration of releasing STN videos to the other support groups that were not in the study and even HIV-negative women to watch these storytelling videos if we are to prevent CC in Malawi.

Feasibility and acceptability of using computer- and interviewer-assisted data collection

All participants including both literacy and illiteracy completed computer-based interviewer-administered participant questionnaires at the baseline and three postobservations and demonstrated the evidence of feasibility and acceptability. We observed that the participants engaged in watching how their responses were typed or clicked on the tablet. Though there were challenges to require additional time for training in use of tablets in limited electricity and internet connections in Malawi rural areas. We developed alternative strategies by uploading survey questions on tablets and fully charging them the previous night. When we returned after data collection to the research center where there was steady internet, we uploaded the data to stream.

Feasibility and reliability of using self-report and health passport review

VIA uptakes were measured through self-report and health passport record review at Observations 3 and 4. At Observation 3, the 2-month point of postintervention data collection, it was found that 25 participants had already received VIA screening when data collectors reviewed their health passport to assess the status of VIA uptake, the primary outcome. This study provides new evidence that the health passport

a χ^2 , Fisher's exact test, Kruskal-Wallis test, or Analysis of Variance was used to detect the significant difference between Arm 1, Arm 2, and Arm 3.

 $^{^{\}rm b}$ K = Malawian Kwacha. US \$1 was 750 K at the time the study was implemented.

offers a rigorous, objective method of measuring screening uptakes in Malawi that have seldom been reported before. We learned that there is a lack of knowledge about differentiating types of diagnostic and women's examinations among Malawian women, so in future studies, an information section should be provided for potential participants and recruiters to explain similarities and differences between VIA or pap smears and other women's vaginal examinations.

Preliminary outcome

The data of 25 participants who had already received VIA screening were not included in the evaluation of preliminary effectiveness of the intervention. Among 154 participants without previous CC screen history, 44.2% of participants reported at the 2-month follow-up that they received a CC screen after the intervention (Table 2). Both arms 1 and 2 had nearly three times the rate of receiving VIA than those in Arm 3 (59.6% and 55.8% vs. 20.0%, P = 0.01) at 2-month follow-up. Though additional VIA uptakes were observed between 2- and 6-month followups among all groups, no significant difference among groups was detected. When within-group uptake rate changes were evaluated with the McNemar's test, Arm 1 and Arm 2 reported statistically significant differences in the changes of the CC screen uptake rate between baseline to 2-month follow-up and 2-month and 6-month follow-ups (P < 0.05). All groups showed high levels of intention of receiving CC screen across the observation times (Table 3). Among 154 participants without previous CC screen history, 148 completed knowledge scale. All groups demonstrated significant improvement of perception of knowledge about risk factors and CC from baseline to postintervention for all arms and were retained well until the 6-month follow-up. When the knowledge scores were compared among arms by Analysis of Variance, the significant difference was detected only at the same-day postintervention evaluation in the CC knowledge score (P < 0.05) (Table 4). However, the significant difference did not maintain at 2-month and 6-month follow-ups.

Table 2VIA uptakes over time by intervention condition.

	Total $n = 154$	Arm 1 n = 47	Arm 2 n = 52	Arm 3 n = 55	P value ^a
CCS uptakes					
Obs.1 to Obs.3	68 (44.2)	28 (59.6)	29 (55.8)	11 (20.0)	< 0.001
Obs.3 to Obs.4	36 (23.4) ^b	$10(21.3)^{b}$	$12(23.1)^{b}$	14 (25.5)	0.9
Obs.1 to Obs.4	104 (67.5)	38 (80.9)	41 (78.8)	25 (45.5)	< 0.001

Data are n (%). Obs.1 = Observation 1 (baseline), Obs.3 = Observation 3 (2-month follow-up), Obs.4 = Observation 4 (6-month follow-up).

Table 3Intention of receiving CCS over time by intervention condition.*

	Total	Arm 1	Arm 2	Arm 3
Obs.2	n = 154	n = 47	n = 52	n = 55
	151 (98.1)	46 (97.9)	50 (96.2)	55 (100.0)
Obs.3	n = 68	n = 14	n = 17	n = 37
	68 (100.0)	14 (100.0)	17 (100.0)	37 (100.0)
Obs.4	n = 48	n = 9	n = 11	n = 28
	47 (97.9)	9 (100.0)	10 (90.9)	28 (100.0)

Data are n (), Obs.2 = Observation 2 (same-day post-intervention), Obs.3 = Observation 3 (2-month follow-up), Obs.4 = Observation 4 (6-month follow-up).

Discussion

This pilot RCT study was conducted to assess feasibility, acceptability, and preliminary effectiveness of the mHealth-delivered STN intervention to increase CC screen uptakes among Malawian WLWHIV. The findings demonstrate evidence of the feasibility of the study regarding recruitment, retention, and acceptability. Fifteen out of 61 HIV support groups were approached, and all accepted to participate in the study. This study recruited 179 out of its target of 180 participants within the initial threemonth period of the two-year funded study and achieved a retention rate of 93.3% completing all study assessments. These findings validate our culture-specific and group-tailored strategies including collaboration with officers from the District Council and HIV-support-group leaders to select data collection times and locations convenient to the participants. The implementation of the pilot RCT was delayed due to the COVID-19 pandemic. Malawi had not enforced a full lockdown but instead practiced sensitive measures with distancing in daily life; cancellation of public events; and decongesting workplaces and public transport. 47 We learned that HIV support groups were not active as they were pre--COVID-19, so we ascertained their activity levels by evaluating whether they had regular support-group meetings and having had an active membership of greater than 15 to satisfy inclusion criteria. We developed protocols to assure safety of the study participants and data collectors following the guidelines from the Malawi government. Most study population live in rural areas surrounded by their farmlands and use bicycles or travel on foot for HIV-support-group meetings. We selected data collection locations close to participants' homes and at times convenient for them so that the participants could work on the farm before the study or after completion of the study. We also arranged bicycle-taxi service for transportation and incentives.

The findings of this study demonstrate the feasibility and acceptability of mHealth delivery by both data collectors and the participants. We observed that the eyes of most participants were glued to the screen of tablets, and they were actively engaged in watching the videos and how the data collectors marked the answers on the tablets. Both participants and data collectors stated that the stories are very enlightening because the storytellers are Malawian WLWHIV, and they can easily relate them to themselves and to their mothers or sisters. One participant wept while watching the STN videos and stated that "if I knew this earlier, I would not let my mom die so soon." The participant gained knowledge about risk factors and symptoms of CC and associated one storyteller with her mother. She wished she could have watched this video earlier so she could protect her mother from dying from CC. This finding is in line with other studies that have showed that exposure to health education videos can improve healthrelated behavior. 18,20,48

Regarding technical skills to use computer-assisted data entering, though data collectors had experiences using smartphones, they had not acquired the foundation and technical skills, so that training was necessary. Originally, we planned to conduct a one-day training session, but we learned that the speed and competency of the data collectors was very low, and we decided to extend the training session for three days. Other studies also found that technology-use requires a focus on training and on the competency of the data collectors. ^{49,50} The tablets were given to each data collector to practice at home to improve their skills in using them. The use of computer-assisted data entering was very successful to real-time data, data coverage, and respondent acceptance.

Although the selection of sample size for this pilot trial was not powered for significance, the findings showed the preliminary effectiveness of the intervention measured with VIA uptakes was significantly increased in the intervention groups of Arm 1 and Arm 2 compared to control group, Arm 3 at 2-month postintervention follow-up. The preliminary effectiveness of the intervention indicates that the one-time 30-min session was feasible and effective as it resulted in more than three times higher VIA uptakes than those of the control group. The three-arm design is a strength, allowing us to assess the effects of mHealth and STN approaches

 $^{^{\}rm a}$ $\chi^{\rm 2}$ was performed for between-group comparison.

 $^{^{\}rm b}$ P<0.05 when McNemar Test was performed for within-group comparison regarding changes of the update rates between Obs. 1 and Obs. 3; Obs. 3 and Obs. 4; Obs. 1 and Obs. 4.

CCS, cervical cancer screening.

 $^{^{*}}$ VIA intention was asked to all participants for Observation 2 and participants who did not receive VIA for Observation 3 and 4.

Table 4Knowledge level over time by intervention condition.

	Total $n = 148$	Arm 1 n = 46	Arm 2 n = 50	Arm 3 n = 52	Difference by arms
RF knowledge					
Obs.1	6.46 (3.36)	6.57 (3.34)	5.92 (3.54)	6.88 (3.17)	F(2, 145) = 1.09
Obs.2	8.19 (2.56)**	8.46 (2.58)**	7.76 (2.72)**	8.37 (2.36)**	F(2, 145) = 1.08
Obs.3	8.61 (2.68)*	8.63 (2.48)	8.28 (2.26)	8.92 (2.39)	F(2, 145) = 0.94
Obs.4	7.96 (3.37)	8.13 (3.57)	8.3 (2.96)	7.48 (3.58)*	F(2, 145) = 0.84
CC knowledge					
Obs.1	6.8 (3.11)	6.54 (3.15)	6.1 (3.41)	7.54 (2.72)	F(2, 145) = 2.88
Obs.2	8.36 (2.13)**	8.59 (2.18)**	7.56 (2.41)**	8.88 (1.65)**	$F(2, 145) = 5.54^{a}$
Obs.3	8.46 (2.72)*	8.41 (2.38)	8.86 (1.86)**	9.1 (2.11)	F(2, 145) = 1.26
Obs.4	8.14 (3.47)*	8.22 (3.45)	8.46 (3.14)	7.73 (3.84)*	F(2, 145) = 0.58

Data are mean (standard deviation). Obs.1 = Observation 1 (baseline), Obs2 = Observation 2 (same-day post-intervention), Obs.3 = Observation 3 (2-month follow-up), Obs.4 = Observation 4 (6-month follow-up).

separately. We did expect participants receiving a combination of the STN and mHealth intervention would better increase their CC screen uptakes and knowledge risk factors and CC than those of who only received the mHealth intervention; however, there was no difference in outcomes between these two intervention groups (arms 1 and 2). We interpreted this to the fact that watching videos on a tablet might attract the participants to engage in didactic health education without stories. Regardless of types of delivery modes, knowledge was improved in all groups; however, improved knowledge was not able to increase VIA uptakes in the control group as it did for those of the intervention groups. As for the placebo control group, nonnarrative educational materials, approached individually rather than in a group to follow COVID-19 guidance on social distancing, might result in increased attention to educational materials and have differing advantages over the group approach. ⁵¹

There is concern about the limited scientific premise and purported feasibility for an mHealth intervention in Sub-Saharan Africa because in most rural areas, less than half the population has access to electricity and Wi-Fi connection. With knowing the limited availability and accessibility of IT, we developed an intervention reflecting these issues while responding to their desire to be part of mHealth that is a one-time intervention session instead of multiple sessions and delivered it on uploaded tablets, not streaming. It appears that the participants perceived watching videos on a tablet as more than participation in the research to connect with the outside world and perceived this with pride and accomplishment by participating in this interactive process of watching videos and entering their answers into the computers.

It is notable that Arm 2, nonnarrative information-reading intervention condition also performed nearly as well as the primary STN intervention. While we were not initially treating this intervention as a control, it is possible that the information-reading videos by educated Malawian women at mHealth context were engaging enough even without narratives.

Implication for nursing practice and research

This finding serves to provide a view of what might be a less costly (in terms of developmental costs) but nearly effective intervention for increasing knowledge and uptake of CCS. Also, all the three groups showed high levels of intention to receive VIA, and it is plausible that some of the initial effects might be caused by special attention given to those not only receiving the intervention but also control conditions. We did, however, receive strong feedback from study participants in Arm 1 who urged the research team through their HIV-support-group leaders to move forward with the intervention to other Malawian women including women without HIV infection. This finding suggests that the extra work associated with creating these personal-story videos is worth continuing

to explore, examining outcomes in a larger RCT comparing the STN to nonnarrative education, and examining comparative costs. The potential for support for dissemination due to this enthusiastic community buy-in from our CAB and others may be as important as the message delivery to be engaging and influential on behavior.

Limitations and strengths

As for the strengths, first we developed an interactive, STN intervention based on authentic stories from Malawian WLWHIV, community leaders, and healthcare providers that encompassed health message domains in a situation-specific theory. Second, we used human-centered participatory methodology that engaged CABs and local star storytellers and a rigorous adaptation process collaboratively which was based on the principle that people who face problems everyday are the ones who hold the key to their answers and will enhance mutual respect and collaborative ownership of the research process and product. Third, we integrated the intervention of CC screen into the HIV-support-group system already in place in Malawi. However, utilizing the HIV support system could be a limitation as the findings will not be applied to Malawian WLWHIV who do not attend HIV support groups and Malawian women without HIV infection. Regarding delivery of the intervention, due to the social-distance policy during the COVID-19 pandemic, we delivered the intervention individually rather than as a group intervention as planned. Thus, the effectiveness of the STN intervention might be different if the intervention was implemented at a group level.

Conclusions

The results suggest STN video to be a feasible and acceptable CC screen intervention in Malawi. The feasibility and the preliminary results of the effectiveness of the proposed study indicate scaling up to a larger study to test the STN intervention more broadly to promote CC screen uptake through community dissemination channels/support to reach a larger population, compared to the "usual-care" nonnarrative education videos. While we saw minimal difference in the uptake of VIA between these two mHealth interventions, it is possible that, as the CAB members stated, the participation of the native star storytellers in the content production of STN fosters ownership of the video content and increases the likelihood that the produced video will be introduced more widely in the community as well as have an impact on women to go for screening. Multiple dissemination pathways and modification of the content are critical to ensure scalability and longterm impact of the STN intervention on preventing deaths due to CC in Malawi.

CC, cervical cancer; RF, risk factor.

^{*}P < 0.05 and **P < 0.001 when t test was performed for within-group comparison for changes in scores from previous data collection (e.g., baseline vs. Same Day-Post-Inv, Same Day-Post-Inv vs. 2 Ms-Post-Inv vs. 6 Ms-Post-Inv).

 $^{^{\}mathrm{a}}$ P < 0.05 when Analysis of Variance was performed for between-group comparison.

Ethics statement

This study was approved by the institutional review board of a university in the Northeast United States (IRB No. 2019250) and a university in Malawi (IRB No. P.o4/2011/011). All participants provided written informed consent.

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CRediT author contribution statement

H.L. conceived, designed, and directed the study and took the lead in writing the manuscript. J.T.M. was in charge of the on-site research activities and assisted in writing the manuscript. M.S.M. contributed to meaand surement development intervention development implementation. L.S. supervised data analysis. L.L., A.M., J.N., and Y.M provided contextual guidance on measurement and intervention development. J.F., L.Z., E.S. provided feedback on research activities throughout the study. D.K. contributed to measurement and intervention development, data collection, data analysis, and manuscript writing. All researchers reviewed the manuscript and provided critical feedback on the manuscript. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author, Professor Haeok Lee. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

Declaration of Generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

Declaration of competing interest

All authors declare no conflicts of interest. Professor Haeok Lee, the corresponding author, serves on the editorial board of the *Asia-Pacific Journal of Oncology Nursing*. The article underwent standard review procedures of the journal, with peer review conducted independently of Professor Lee and their research groups.

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