Original Research Article

Cancer Control
Volume 29: 1–17

DOI: 10.1177/10732748221089480
journals.sagepub.com/home/ccx
SAGE

The Effect of Peer-Led Navigation Approach as a Form of Task Shifting in Promoting Cervical Cancer Screening Knowledge, Intention, and Practices Among Urban Women in Tanzania: A Randomized Controlled Trial

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Abstract

Background: Even though the government's priorities in preventing cervical cancer are implemented in urban areas, the screening rate remains unsatisfactory at 6%, compared to 70% recommended by the world health organization. The ongoing public health education has not resulted in sufficient screening rates. The study aims to assess peer-led navigation (PLNav) in promoting cervical cancer screening knowledge, intention, and practices among urban women in Tanzania. Since PLNav is the form of task shifting, it involves delegating cervical-cancer-related tasks from healthcare professionals to community health workers (CHWs).

Methods: It is a community-based randomized controlled trial conducted in Dar es Salaam in Tanzania March-Sept 2020. The PLNav involved the CHWs delivering health education, counselling and navigation assistance to community women (COMW). The CHWs help women who have never undergone cervical cancer screening (CCS) and those who have undergone CCS but with a precancerous cervical lesion to overcome screening barriers. The data related to PLNav were analyzed by descriptive statistics, an independent-samples t-test, repeated measures ANOVA and linear regression.

Results: The repeated measures ANOVA across time showed that PLNav intervention on mean knowledge score changes was statistically significant in the intervention group compared with the control group's usual care, [$F(1, 43) = 56.9$, $P < .001$]. At the six-month follow-up, 32 (72.7%) out of 44 participants from the intervention group had screened for cervical cancer, and only one participant (2.3%) from the control group screened. The PLNav intervention on CCS uptake changes was statistically significant in the intervention group compared with usual care in the control group [$F(1, 43) = 100.4$, $P < .001$]. The effect of time on CCS uptake in the intervention and control groups was statistically significant [$F(1.64, 70.62) = 73.4$, $P < .001$].

Conclusion: Peer-led navigation (PLNav) was effective in promoting cervical cancer screening knowledge, intention, and uptake.

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Keywords
cervical cancer, community health workers, health education, knowledge, patient navigation, peer-led navigation, screening

Introduction

In 2020, the new cases of cervical cancer among women worldwide was 604 127, with Asia (58.2%), Africa (19.4%), Latin America and the Caribbean (9.8%), Europe (9.6%), and Northern America (2.5%), while the mortality was highest in Asia 199 902 (58.5%) and Africa 76 745 (22.5%).[1] In Africa, 40% of new cases of cervical cancer occur in East Africa.[2] Even though WHO emphasizes that every country member integrate and strengthen screening services within their health care systems, cervical cancer screening is still unsatisfactory in developing countries.[3]

Cervical Cancer and Cervical Cancer Screening (CCS) in Tanzania

Cervical cancer is the number one causing cancer-related deaths in Tanzania than other types of cancers, with an estimated incidence of 5 times higher than the combined incidences of common male cancer and female cancer.[4] The WHO and another previous study reported that the incidence rate of cervical cancer in Tanzania is 40.6: 100 000 compared to 25.7:100 000 in Africa.[3,5] It is estimated that the incidence of cervical cancer in Tanzania is the fifth-highest globally, and cervical cancer mortality is the eighth in the world.[4] Even though the reduction of cervical cancer mortality among women screened for cervical cancer is 91% in Western Europe, and (41% and 84%) in Northern Europe,[6] the number of women screened for cervical cancer in Tanzania aged between 30 and 50 years remains unsatisfactory, with participation at 6–21% of the population,[7] lower compared to 70% recommended by the WHO.[8] Many studies have recently been carried out in rural areas to examine barriers to screening with less attention in urban areas. Even though the government and non-governmental organizations (NGOs) efforts and priorities in preventing cervical cancer are being implemented in urban areas, the screening rate remains unsatisfactory,[9] with only 6% of urban women screened,[10] indicating the need to conduct the study on urban women.

Screening Hindrance and Solutions

Knowledge deficit of cervical cancer[11] and poor attitude of screening[12] are reported as screening hindrances. The Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC), in collaboration with the medical women association of Tanzania (MEWATA), conducts public health education to promote awareness of cervical cancer screening and to overcome the knowledge deficit as a screening hindrance.[13]The public health education delivered to clients or communities is ineffective because there is no national health policy about CCS,[14] shortage of healthcare workers,[15] and lack of follow-up. Therefore, the current public health education has been focussing only on increasing the knowledge of cervical cancer among women, but it has not resulted in sufficient screening rates. This indicates the presence of multiple screening hindrances that have not been successfully addressed by public health education.[16] Therefore, the new intervention approach should be adopted or introduced to address multiple screening hindrances collectively.[17]

Peer-Led Navigation (PLNav)

Due to increased barriers in the uptake of breast and colorectal cancer screening of services such as financial and access barriers, communication and information barriers, medical system barriers, fear, distrust, and emotional barriers,[18] Freeman introduced patient navigation/peer-led navigation (PLNav) approach in 1990 to promote behaviour in uptake screening services.[19] This approach is widely applied to promote CCS behaviour of women.[19] In many studies, peer navigators are commonly entitled as community health workers (CHWs).[20-24] The CHWs are trained native lay people living in the same community and helping women who have never undergone cervical cancer screening (CCS) and those who have undergone CCS but with precancerous cervical lesion to overcome screening barriers.[25-28] CHWs should have graduated from high school or college level[21,25] and received the training from nurses and physicians.[21,26,29,30]

Task Shifting in Tanzania

Task shifting is the delegation of health-related tasks from highly qualified health workers to less trained personnel.[31] The redistribution of tasks aims to make more efficient use of the available human resources for health.[32] The task shifting in Tanzania has been performed mainly by physician's tasks delegated to nurses, and nurse's tasks are delegated to medical attendants.[33] The studies about delegation of cervical-cancer-related tasks from healthcare professionals such as nurses or doctors to CHWs in Tanzania are insufficient, putting the need to explore more about it. Specific objectives are (i) to assess the effect of peer-led navigation (PLNav) approach as a form of task shifting in promoting cervical cancer screening knowledge (ii) to assess the effect of peer-led navigation (PLNav) in promoting cervical cancer screening intention, and (iii) to assess the effect of peer-led navigation (PLNav) in promoting the

uptake of cervical cancer screening among urban women in Tanzania based on the theory of planned behaviour (TPB), health belief model (HBM), and diffusion of innovation theory (DOI).TPB and HBM were used to predict and promote screening intention and screening uptake, while DOI was used in COMW's behaviour change and implementation of screening uptake.[34]

Methods

It is a community-based randomized controlled trial conducted in 6-months (March-Sept 2020), and the effect of PLNav intervention was evaluated in the 3-monthly period. The trial registration: https://pactr.samrc.ac.za (PACTR202003570419141), registered on 26th February 2020. It involved developing an intervention package, recruitment and training of community health workers (CHWs), recruiting community women (COMW), and PLNav intervention delivery. The reporting of this study conforms to the CONSORT statements.[35,36] The study protocol obtained the ethical clearance from The University of Dodoma- Directorate of Research and Publications, Consultancy and Institutional Collaboration in Tanzania.

The Development of an Intervention Package

The draft of the interventional package contained the training manual of CHWs and the navigation manual of COMW. A principal investigator developed the training manual to help a licensed nurse train or prepare CHWs to deliver PLNav to COMW. In contrast, the navigation manual was developed to help CHWs provide PLNav to COMW, including health education information, counselling content, and navigation care. Based on WHO community health worker's training manual[37] and information collected through systematic review in a previous study,[38] the first draft of the intervention package was developed using the theory of planned behaviour (TPB), health belief model (HBM), and diffusion of innovation theory (DOI).The first draft was later revised based on the cross-sectional study and a qualitative study conducted by a principal investigator. The details of the cross-sectional study can be accessed.[39]The training manual of CHWs and navigation manual of COMW contained the content to be covered, participant recruitment procedures, guidance for facilitators, and how PLNav was delivered.

Recruitment and Training of Community Health Workers (CHWs)

Twelve women who had participated in the previous cross-sectional quantitative study with ordinary level (n = 9), high school level (n = 2), diploma level (n = 1), and had previously screened for cervical cancer were contacted through phone calls. Only four women who had ordinary secondary education levels were willing to participate in the study, while eight were not ready because of their busy schedule, and others self-reported to afraid of their husbands. Four women willing to participate in the study were physically visited at their homes one day before the training, provided consent, completed the baseline questionnaire, told everything about the study process, and were invited to the training the next day. The following are inclusion criteria of CHWs; they were from the same community where PLNav intervention was to be conducted.[25-27] They had previously screened for cervical cancer having screening experiences that would help promote screening practices among community women and willing to participate in the study.[20,40] They had completed secondary school, high school, or college level.[21,25] They had a permanent residence with no plan to migrate to other regions during a 6-month study period, speak the native language Swahili, and comprehend the information. CHWs were excluded from the study if they had any known mental illness, difficulties in speaking, mobility problems and were unwilling to participate. The developed interventional package contained a training manual of CHWs to equip CHWs with basic knowledge of cervical cancer, screening modalities and delivering PLNav intervention to the community women (COMW).[20,27,29,30] The training of CHWs was conducted in 3 days consecutively with 7-educational sessions.[21,23,27,29,30,41] The training of CHWs was conducted in the native Swahili language[21,26,29,30] and facilitated by a bachelor degree nurse.[23,26,30] Interactive role-plays and discussions were performed at the end of each session to facilitate learning.[20]

Recruitment of Community Women (COMW)

COMW were recruited from Dar es Salaam in Kawe ward. The ward has 89 941 total population, with 46 487 women.[42] The following were the Inclusion criteria of COMW; the study recruited COMW aged 21-50 years old because this age group is at higher risk for cervical cancer disease,[20-25,27,30,40,43] which is also the age group to uptake CCS in Tanzania.[44-46] They had no previous history of cancer or current medical problem that could impede them from participating in the study.[22,25,27,40,43] They had no previous CCS tests[24] because PLNav intervention is effective for women who have never screened before and not received cervical cancer health education.[23,47-49] They could speak native Swahili language,[21,23,25] with no plan to change Dar es Salaam's living residence during the study period six months,[21,25,40] non-pregnant[24] and willing to participate in study.[23-25] COMW were excluded from the study only if they could not comprehend the information due to mental illness, mobility difficulties, and those absent at the time of collecting baseline data. Recruitment was conducted house-to-house visits by four research assistants to search for eligible COMW. Systematic random sampling was applied to select houses from which one COMW was drawn per house. The study was conducted in 'Mzimuni street', which had 2010 houses and the desired sample size from this area was 88. The

sampling interval was calculated by dividing the population size by the desired sample size that resulted to (3600/88) = 41. Therefore, every 41st house was selected. In a situation where more eligible women were found in one house, simple random sampling through the balloting method was performed to select one among them, and if no eligible COMW was found in the house, the researchers moved to the next house. In the recruitment process, 162 COMW were visited, 88 COMW were willing to participate in the study, some women refused to participate (n = 48), and others did not meet the inclusion criteria (n = 26). The number of individuals who declined consent was higher than the sample size per group because the research involved private parts (cervical cancer screening), which might have been perceived by some people as a shameful practice. All COMW willing to participate in the study signed the written consent form and completed the pre-test questionnaire on the same day of the visit. The purpose of consent was to ask respondent's participation and informing them about their safety during the study.

PLNav Intervention

The next day after the house-to-house visit, 44 women in the intervention group were contacted through phone calls. COMW were informed about the PLNav intervention that would be offered to them. The intervention included health education about cervical cancer and CCS, counselling to women who failed to screen according to the scheduled appointments, navigation care like escorting women to the screening centre, and taking care of children when their mothers went for screening. Since the intervention began with health education, COMW were informed that the health education session was to be conducted by CHWs the next day, and all details about the place and time were provided. Four CHW each conducted a one-time group education session to 11 COMW,[21-25,43] that lasted for 2 hours.[23,43] The delivery of health education was guided by the manual that contained 3 sessions, introduction session (20 Minutes), learning about the female genital organs (20 Minutes), cervical cancer meaning, causes, risk factors, signs and symptoms (50 Minutes), and prevention of cervical cancer (30 Minutes).[21-24,26,27,29,43] The sessions were conducted with flipcharts to facilitate learning.[20-25,27,30] At the end of each session, CHWs asked questions and facilitated the discussions to promote interactive learning. On the same day, CHWs scheduled appointment dates for women to attend the nearby dispensary to uptake screening.[26,27] The CHWs conducted a follow-up by telephone or home visit two weeks after delivering education to determine whether COMW had gone for screening tests.[21-26,43] After that, the follow-ups were conducted monthly. The purpose of follow-up care was firstly to identify COMW's screening hindrances and provide possible solutions. For instance, counselling was provided to promote positive health beliefs, screening intentions, clear existing misconceptions, and resolve doubts among COMW who had missed the appointment dates and who had difficulty in making screening decisions. Furthermore, during follow-up, CHWs provided navigation care. For instance, COMW who feared going alone to the screening centre were escorted by CHWs.[20,23,25,26,30,43] CHWs assisted some COMW who needed someone to take care of their children when attending the screening centre. 44 COMW randomized into the control group continued to receive the routine (usual care) health education on cervical cancer and its prevention through the ongoing national CCS awareness raising and other channels.[21-23,27,40,43] However, after exiting the study at six-month follow-up, participants in the control group were provided with the opportunity to receive PLNav same as in the intervention group.

Counselling Care

Counselling is the guidance in resolving personal or psychological problems.[50] Counselling care aimed to promote positive health beliefs and screening intention. Therefore, the counselling was delivered in the form of talk, discussing the benefits of cervical cancer screening, asking what kept them away from going for screening, encouraged them to talk about their worries if they had any, reassured them that they need not be scared as the screening tests are simple, do not take much time and are not painful, and cleared their misconceptions if any.

Outcome Variables

The primary outcomes include the effect of PLNav on the knowledge level and uptake of cervical cancer screening within the allocated period of 6 months. Secondary outcomes included the effect of PLNav on changes in awareness about cervical cancer, health beliefs, subjective norms, perceived behaviour control, and cervical cancer screening intention.

The Sample Size of COMW

The sample size for COMW was calculated based on the formula retrieved from the previous study.[51] $Z\alpha$ = Standard normal deviation (1.96), 95% confidence level, 2β = Standard normal deviate (.84), power at 90% to increase the sample size, πo = Proportion at pre-intervention (47%),[44] and $\pi 1$ = proportion after the intervention (67%).[44] The sample size of 48 COMW was added to its half to obtain more representatives in this study.[52] However, 35% was an expected non-response, and therefore, the actual sample size was 88 COMW.

Randomization of Community Women (COMW)

Eighty eight (88) COMW were randomized in ratio 1:1 into the intervention group (n = 44) and control group (n = 44). A statistician performed randomization by computer through excel RAND function-random numbers-sort. The principal investigator was

blinded at the randomization to avoid bias during analysis. COMW in the control group were blinded as they were not informed of being allocated to the control group and were not told anything related to the ongoing intervention. The intervention group participants were not blinded due to the nature of the intervention.

Data Collection

All participants in both groups were administered a pre-intervention and post-intervention questionnaire. The questionnaire's primary focus was to assess the knowledge level, awareness, screening intention, and health beliefs towards screening after PLNav intervention. Therefore, COMW completed the questionnaire at baseline, three-month follow-up and six-month follow-up.[20,21,23,25,30] Four questionnaires were adopted from the previous studies, knowledge,[53] subjective norms,[54] perceived behavioural control,[55] and health beliefs,[56] and little modification was performed. The tool with 77 items was tested, and the following were the reliability of each component Knowledge level (Cronbach's alpha ~ .92), attitude (Cronbach's alpha ~ .82), subjective norms (Cronbach's alpha ~ .91), perceived behavioural control (Cronbach's alpha ~ .98), and health beliefs (Cronbach's alpha ~ .76). The individual outcome variables were assessed as follows; knowledge level was assessed by 24 items related to cervical cancer meaning, causes, risk factors, and prevention, 2 items were used to assess the cervical cancer awareness, while one item assessed CCS uptake. 24 items assessed screening intention (9 Items assessed attitude, 11 items assessed subjective norms, 4 items assessed the perceived behavioural control), and 27 items assessed the health beliefs.

Data Analysis

COMW's socio-demographic characteristics were analyzed through descriptive statistics (frequencies and proportions) and means. The comparability between intervention and control groups at baseline (T0) was performed through an independent-samples t-test. The effect of PLNav intervention on knowledge level, awareness, screening intention, health beliefs, and CCS uptake across time (T0, T1, and T3) was performed through Repeated Measures ANOVA. Chi-square tests and cross-tabulation were done to determine the association between independent and dependent variables. Linear regression was performed to determine the extent of association between independent and dependent variables and between PLNav intervention and changes in knowledge level, screening intention, health beliefs, and screening uptake in a measure of (Beta)**.**Furthermore, linear regression was performed to determine the extent of association of participant's socio-demographic characteristics (age, number of pregnancies, number of deliveries, marital status, educational level, religion, sexual practices, whether vaccinated, HIV/AIDS status, and health-seeking behaviour) with main study variables**.** The significance level was set at $P^{<}$ .05.

Maintaining Fidelity of the Intervention

For a compelling intervention study, four research assistants were trained to distribute the questionnaire to urban women. The systematic review study, qualitative study and cross-sectional study, and experts' evaluations were initially conducted before intervention study aiming to develop PLNav intervention plan. The data collection tools used throughout the study were reliable and valid. The principal investigator was blinded at the randomization stage of participants into the intervention or control group to avoid bias during analysis. Research assistants who collected data at the pre-test phase were different from those who collected data at the post-test phase; this avoided some researcher's biases.

Results

The Baseline Demographic Characteristics of Participants in the Intervention and Control Groups

44 COMW randomized in the intervention group received PLNav intervention, and 44 COMW in the control group received usual care. Since no loss of COMW, the analysis included 44 COMW in the intervention and 44 COMW in the control group. Refer to participant's flow diagram Figure 1. COMW's age in both intervention and control groups averaged 31 years old and were gravida 2, para 1. A majority of COMW were married 62 (70.5%), received primary school education 55 (62.5%), and belonged to the Islamic religion 45 (51.2%). They had never screened for cervical cancer, and 87 (98.9%) were never vaccinated for cervical cancer. 83 (94.4%) of COMW reported having no HIV infection, while most of them had no regular habit of checking their health status 49 (55.7%). 76 (86.4%) reported having never received health education regarding cervical cancer screening in both groups. Concerning the baseline comparability, there was no significant difference between the intervention and control groups in COMW's age, number of pregnancies, deliveries, marital status, occupation, sexual practices, husband education, husband occupation, and number of current sexual partners. Furthermore, the two groups had no significant difference in cervical cancer vaccination, HIV status, regularly checking the health status, and receiving health education of cervical cancer screening. Most important, COMW in both groups had never screened for cervical cancer. Refer to Table 1. Moreover, there was no significant difference in the knowledge level of cervical cancer, screening intention, and health beliefs between COMW in the intervention and control groups at baseline (T0) (Figures 2 to 6).

Effect of PLNav on Awareness

At baseline (T0), most of the COMW from both intervention and control groups had heard about cervical cancer

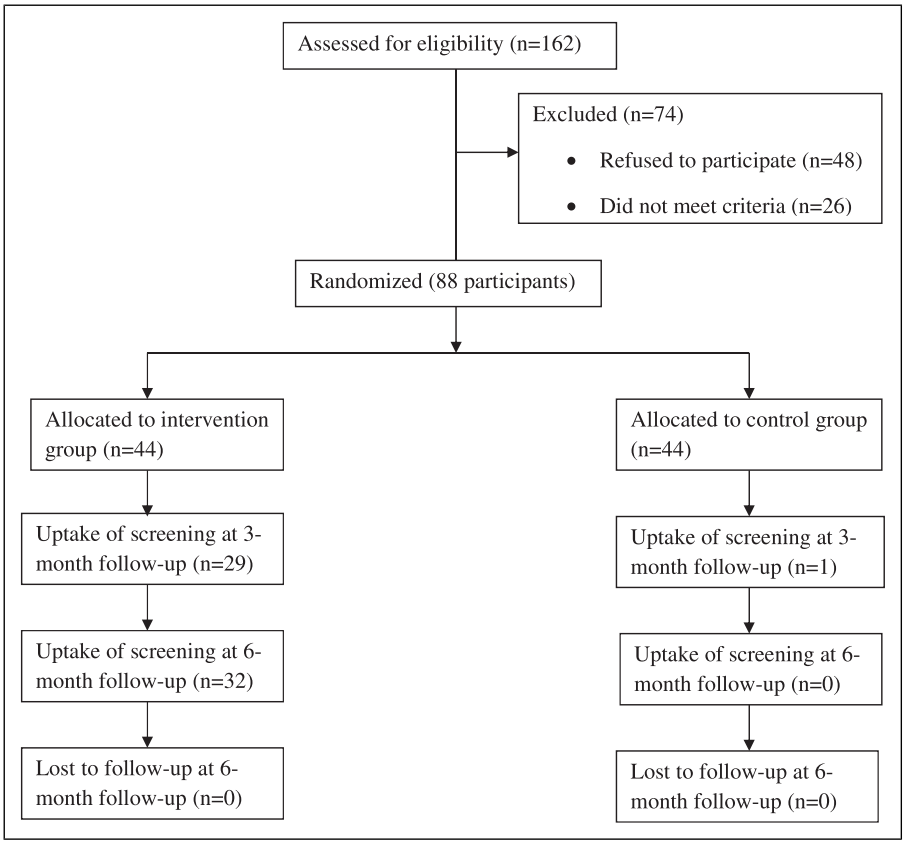

Figure 1. The participants flow diagram.

(77.3% and 86%), respectively. However, few COMW, 45.5% from the intervention group and 40.9% from the control group, had heard about cervical cancer screening. Therefore, at baseline (T0), there was no significant difference in awareness between intervention and control groups t (86) = −.303; P = .762; 95% CI: −.343, .252. The Repeated measures ANOVA with Greenhouse-Geisser correction across time showed that the effect of PLNav intervention on mean awareness score changes was statistically significant in the intervention group (T0 = 3.2 ± .7, T1 = 4.0 ± .0, and T2 = 4.0 ± .0), compared with the control group's usual care (T0 = 3.3 ± .66, T1 = 3.3 ± .7, and T2 = 3.3 ± .7), [F (1, 43) = 14.4, P < .001]. At three-month follow-up, the mean awareness scores in the intervention group increased 23.84% (3.23 to 4.0 points) compared with 1.53% (3.27 to 3.32 points) in control, while at six-month follow-up, the findings in both groups remained the same as in three-month follow-up. The effect of time on mean awareness scores in the intervention and control groups was statistically significant [F (1, 43) = 44.4, P < .001], and the PLNav intervention on changes of mean awareness scores interacted with time [F (7.76, .18) = 44.0, P < .001]. Across time, significant mean differences were observed between T0 and T1 (md = .4), P < .001, and between T0 and T2 (md = .4), P < .001, but there was no significant mean difference between T1 and T2. Refer to Table 2 and Figure 4. After linear regression, there was no significant association between participant's socio-demographic characteristics with changes of cervical cancer awareness in both groups.

Effect of PLNav on Knowledge

Many of the participants at a baseline (T0) had a knowledge deficit of cervical cancer. Among 18 out of 24 items, each had less than 50% of COMW from intervention and control groups with knowledge about cervical cancer. At baseline (T0), there was no significant difference in knowledge level among COMW between intervention and control group t (86) = −.524; P = .602; 95% CI: −7.196, 4.196. The repeated measures ANOVA with Greenhouse-Geisser correction across time showed that the effect of PLNav intervention on mean knowledge score changes was statistically significant in the intervention group (T0 = 43.8 ± 12.9, T1 = 70.5 ± 2.8, and T2 = 70.9 ± 1.4), compared with the control group's usual care (T0 = 45.3 ± 13.9, T1 = 45.8 ± 13.9, and T2 = 45.8 ± 13.9), [F (1, 43) = 56.9, P < .001]. Across time, at 3-month follow-up (T1), mean knowledge scores in the intervention group increased 60.8% (43.8 to 70.5 points) compared to .95% increase (45.3 to 45.8 points) in the control group. At six-month follow-up (T2), mean knowledge scores in the

Table 1. Distribution of Socio-demographic Characteristics of Participants at Baseline, Mzimuni-Dar es Salaam, 2020.

Characteristic	Total (n = 88), No. (%) or mean ± SD	Intervention (n = 44), No. (%) or mean ± SD	Control (n = 44), No. (%) or mean ± SD	*P*
Age (range = 21–50)	31.32 ± 7.46	32.02 ± 7.32	30.61 ± 7.60	.38*
Number of pregnancies (range = 0–7)	2.1 ± 1.62	2.44 ± 1.57	1.76 ± 1.67	.054*
Number of deliveries (range)	1.84 ± 1.48	2.02 ± 1.33	1.66 ± 1.63	.255
Marital status				
Single/Divorced/widowed	26 (29.55)	9 (20.5)	17 (38.6)	.075*
Married	62 (70.45)	35 (79.5)	27 (61.4)	
Participant's occupation				
Peasant/Agriculture	1 (2.3)	1 (2.3)	-	.113*
Employed/Self-employed/Business	52 (59.05)	24 (54.5)	28 (63.6)	
Housewife	29 (32.95)	18 (40.9)	11 (25.0)	
Unemployed	6 (6.85)	1 (2.3)	5 (11.4)	
Have started sexual intercourse				
Yes	85 (96.6)	44 (100)	41 (93.2)	.403*
No	3	-	3 (6.8)	
Husband education				
University/College/Vocational	10 (11.35)	4 (9.1)	6 (13.6)	.09*
Ordinary secondary/High school education	28 (31.8)	14 (31.8)	14 (31.8)	
Primary school	21 (23.85)	14 (31.8)	7 (15.9)	
Not gone to school	3 (3.4)	2 (4.5)	1 (2.3)	
No husband	26 (29.55)	10 (22.7)	16 (36.4)	
Husband occupation				
Employed/Self-employed/Business	61 (69.35)	34 (77.3)	27 (61.4)	.154*
Have no husband	26 (29.55)	10 (22.7)	16 (36.4)	
Unemployed	1 (2.3)	-	1 (2.3)	
Total current number of sexual partners				
No partner	13 (14.75)	6 (13.6)	7 (15.9)	.701
1 partner	70 (79.55)	36 (81.8)	34 (77.3)	
>2 partners		2 (4.5)	3 (6.8)	
Ever had cervical cancer screening (CCS) test				
Yes	-	-	-	N/A
No	88 (100)	44 (100)	44 (100)	
Are you vaccinated for CC				
Yes	1 (2.3)	-	1 (2.3)	.249*
No	87 (98.85)	44 (100)	43 (97.7)	
Are you HIV positive				
Yes	-	-	-	.434*
No	83 (94.35)	42 (95.5)	41 (93.2)	
I don't know	5 (5.65)	2 (4.5)	3 (6.8)	
Do you have the habit of checking your health in hospital				
Yes	39 (44.3)	21 (47.7)	18 (40.9)	.945*
No	49 (55.7)	23 (52.3)	26 (59.1)	

Abbreviation: CCS-cervical cancer screening, CC-cervical cancer.
The test was done by Pearson Chi-Square (χ^2).
*P > .05.

intervention group were .64% (70.5 to 70.9 points) compared to zero percentage (45.8 to 45.8 points) in the control group. The effect of time on mean knowledge scores in the intervention and control groups was statistically significant [F (1.03, 44.23) = 201.1, $P < .001$]. The PLNav intervention on changes of mean knowledge scores interacted with time [F (1.03, 44.18) = 180.6, $P < .001$]. Across the time, there were significant differences of mean knowledge scores

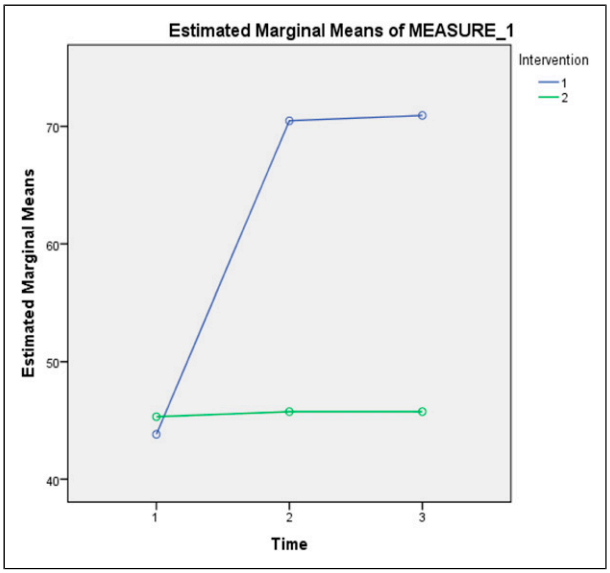

Figure 2. Knowledge changes between intervention and control groups in T0, T1 and T2.

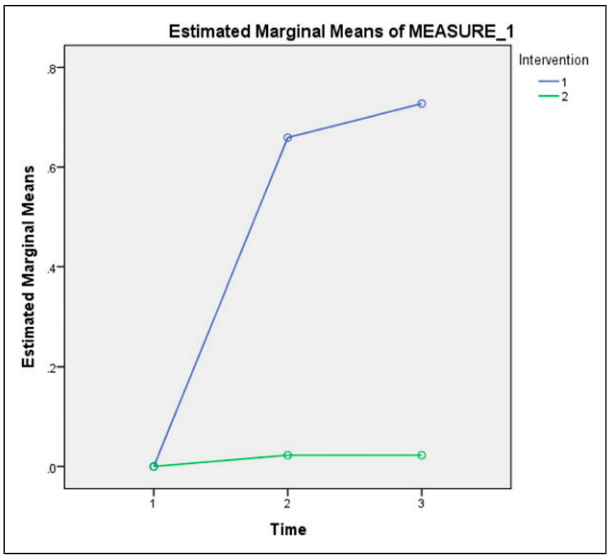

Figure 3. CCS uptake changes between intervention and control groups in T0, T1 and T2.

between T0 and T1 (md = 13.5), $P < .001$, and between T0 and T2 (md = 13.8), $P < .001$, but there was no significant mean scores difference between T1 and T2 (.2), $P = .094$. Refer to Table 2 and Figure 2. The linear regression was performed and found an increased knowledge level in the intervention group at three-month follow-up was associated with increased scores in other variables within the intervention group. 37.7% (Beta = .377) of one score screening intention gain was explained by an increased knowledge level ($P = .012$; 95% CI: .237, 1.785), and 48.5% (Beta = .485) of one score health beliefs gain was explained by an increased

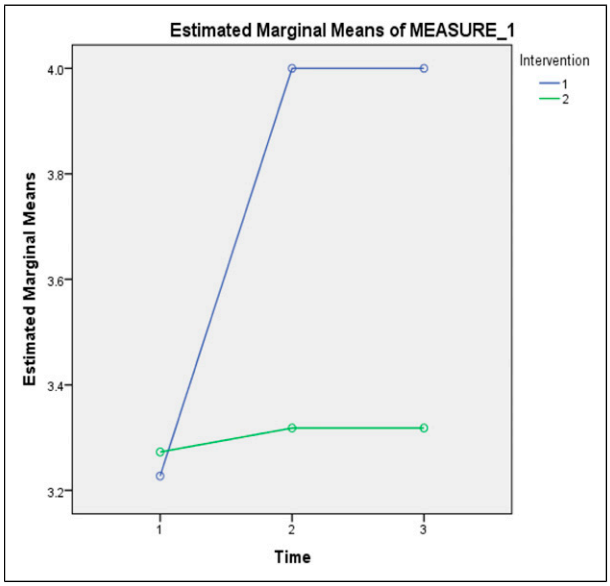

Figure 4. Awareness changes between intervention and control groups in T0, T1 and T2.

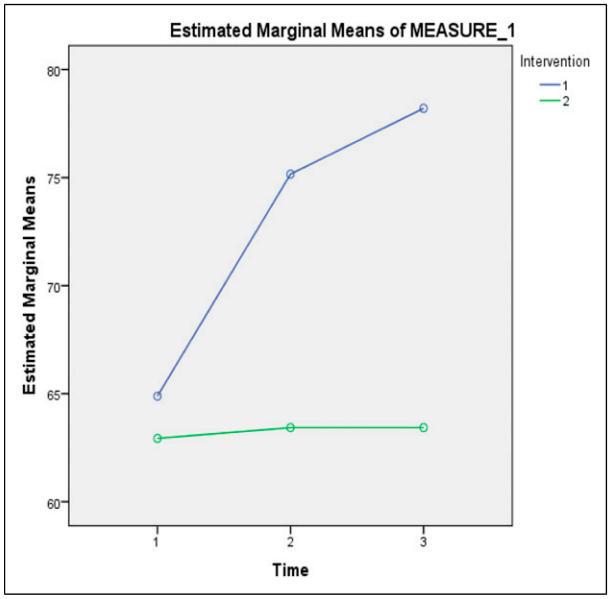

Figure 5. Health belief changes between intervention and control groups in T0, T1 and T2.

knowledge ($P = .001$; 95% CI: .381, 1.357). Refer to supplement Table 1. Meanwhile, at six-month follow-up, 53.3% (Beta = .533) of one score health belief gain was explained by an increased knowledge ($P < .001$; 95% CI: .612, 1.808). Refer to supplement Table 2. There was no significant association of an increased knowledge with other variables within the control group neither at three-month follow-up nor at six-month follow-up. Meanwhile, after linear regression, there was no significant association between participant's socio-demographic characteristics with cervical cancer knowledge changes in both groups.

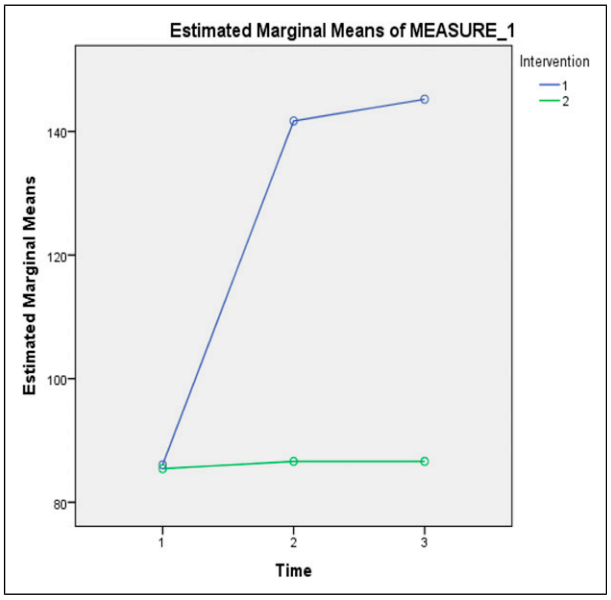

Figure 6. Screening intention changes between intervention and control groups in T0, T1 and T2.

Effect of PLNav on Cervical Cancer Screening Intention

The screening intention was computed by joining scores of cervical cancer screening attitude, subjective norms, and perceived behavioural control. The comparability at baseline (T0) shows no significant difference in screening intention between intervention and control groups t (86) = .075; P = .941; 95% CI: −8.601, 9.273. The Repeated measures ANOVA with Greenhouse-Geisser correction across time showed that the effect of PLNav intervention on mean screening intention score changes was statistically significant in the intervention group (T0 = 86.1 ± 17.4, T1 = 141.7 ± 7.5, and T2 = 145.2 ± 5.3), compared with the control group's usual care (T0 = 85.4 ± 23.9, T1 = 86.6 ± 23.5, and T2 = 86.6 ± 23.5), [F (1, 43) = 106.6, P < .001]. There was a highly significant increase in the intervention group's screening intention at the three-month follow-up. Screening intention in the intervention group increased 64.61% (86.1 to 141.7points) compared to 1.38% (85.4 to 86.6 points) in the control group. At six-month follow-up, screening intention in the intervention group was 2.48% (141.7 to 145.2 points) compared to unchanged scores in the control group. The effect of time on mean screening intention scores in the intervention and control groups was statistically significant [F (1.10, 47.49) = 415.0, P < .001]. The PLNav intervention on changes of mean screening intention scores interacted with time [F (1.09, 47.18) = 343.6, P < .001]. Refer to Table 2 and Figure 6. There were significant mean differences between all times; between T0 and T1 (md = 28.4), P < .001, between T0 and T2 (md = 30.2), P < .001, and between T1 and T2 (md = 1.8), P < .001.Refer to Table 2. The linear regression was performed to determine the extent of the association of variables with increased COMW's screening intention. It was found that at six-month follow-up in the intervention group, 77.7% (Beta = .777) of one score screening intention gain was explained by attitude (P < .001; 95% CI: .954, 1.597), and 67.4% (Beta = .674) was explained by perceived behavioural control (P < .001; 95% CI: 1.28, 2.606). Furthermore, 56.9% (Beta = .569) of one score of screening intention was explained by subjective norms (P < .001; 95% CI: .608, 1.605), and 47% (Beta = .47) was explained by health belief (P = .001; 95% CI: .327, 1.248). In contrast, there was no significant association of COMW's screening intention with knowledge, awareness, screening attitude, subjective norms, perceived behavioural control, and health beliefs in the control group at a three-month follow-up. However, at six-month follow-up, after linear Regression, 77.7% (Beta = .777) of one score screening intention gain was explained by attitude (P < .001; 95% CI: .954, 1.597), 67.4% (Beta = .674) by perceived behavioural control (P < .001; 95% CI: 1.28, 2.606), 56.9% (Beta = .569) by subjective norms (P < .001; 95% CI: .608, 1.605), and 47% (Beta = .47) by health belief (P = .001; 95% CI: .327, 1.248).After linear regression, there was no significant association between participant's socio-demographic characteristics with changes of CCS intention in both groups.

Effect of PLNav on Health Belief

At baseline (T0), eleven out of twenty-seven items, each shows that less than 50% of participants in the intervention group had positive health beliefs about cervical cancer screening, while nine out of twenty-seven items, each show that less than 50% of participants in the control group had positive health beliefs. At baseline (T0), there was no significant difference between intervention and control groups on health belief t (86) = 1.338; P = .185; 95% CI: −.950, 4.859. The repeated measures ANOVA with Greenhouse-Geisser correction across time showed that the effect of PLNav intervention on mean health beliefs scores changes was statistically significant in the intervention group (T0 = 64.9 ± 7.2, T1 = 75.2 ± 5.0, and T2 = 78.2 ± 3.2), compared with the control group's usual care (T0 = 62.9 ± 6.5, T1 = 63.4 ± 6.2, and T2 = 63.4 ± 6.2), [F (1, 43) = 64.1, P < .001]. At three-month follow-up, health belief scores in the intervention group increased 15.83% (64.9 to 75.2points) compared to .79% (62.9 to 63.4 points) in the control group, but at six-month follow-up, health belief scores in the intervention group were 4% (75.2to 78.2 points) compared to unchanged mean scores in the control group. The effect of time on mean health beliefs scores in the intervention and control groups was statistically significant [F (1.3, 56.02) = 125.6, P < .001]. The PLNav intervention on changes of mean health beliefs scores interacted with time [F (1.29, 55.72) = 104.4, P < .001]. Across time, there were significant mean differences between all times; between T0 and T1 (md = 5.4), P < .001, T0 and T2 (md = 6.9), P < .001, and between T1 and T2 (md = 1.5), P < .001. Refer to Table 2 and Figure 5. The linear regression was performed to determine the extent of

Table 2. PLNav Effect on Various Variables.

Category	T1	T2	T3	F-intervention effect	*P*	F time effect	*P*	F time and intervention interaction effect	*P*
Knowledge									
Intervention group	43.82 ± 12.89	70.48 ± 2.81	70.93 ± 1.40	56.88	<.001	201.09	<.001	180.63	<.001
Control group	45.32 ± 13.96	45.75 ± 13.88	45.75 ± 13.88						
Awareness									
Intervention group	3.23 ± .743	4.0 ± 0.0	4.0 ± 0.0	14.448	<.001	44.37	<.001	44.03	<.001
Control group	3.27 ± .66	3.32 ± .67	3.32 ± .67						
Attitude									
Intervention group	27.41 ± 2.47	39.93 ± 5.33	43.32 ± 3.26	233.68	<.001	310.38	<.001	305.91	<.001
Control group	27.14 ± 2.71	27.39 ± 2.89	27.39 ± 2.89						
Subjective norms									
Intervention group	32.5 ± 15.48	74.98 ± 2.72	75.11 ± 2.75	60.15	<.001	339.49	<.001	288.67	<.001
Control group	35.55 ± 20.0	36.39 ± 19.61	36.39 ± 19.61						
Perceived behavioural control									
Intervention group	26.16 ± 4.75	26.77 ± 1.85	26.77 ± 1.85	9.47	.004	0.9	.351	.49	.49
Control group	22.75 ± 8.16	22.84 ± 7.96	22.84 ± 7.96						
Screening intention									
Intervention group	86.07 ± 17.39	141.68 ± 7.54	145.2 ± 5.34	106.63	<.001	415.0	<.001	343.59	<.001
Control group	85.43 ± 23.87	86.61 ± 23.45	86.61 ± 23.45						
Health beliefs									
Intervention group	64.89 ± 7.21	75.16 ± 5.03	78.2 ± 3.19	64.14	<.001	125.6	<.001	104.4	<.001
Control group	62.93 ± 6.48	63.43 ± 6.23	63.43 ± 6.23						
CCS uptake									
Intervention group	-	29 (65.9%)	32 (72.7%)	100.39	<.001	73.43	<.001	71.02	<.001
Control group	-	1 (2.3%)	1 (2.3%)						

Group1 is intervention group, Group 2 is the control group, T1 = Baseline, T2 = 3-month follow-up, T3 = 6-month follow-up.
Data were analyzed by Repeated measure ANOVA, and are presented in mean scores, F, and P-value.
Repeated Measures ANOVA (F) is presented in three categories, Intervention effect, time effect, and intervention and time interaction.

the association of variables with increased positive health beliefs. At six-month follow-up among COMW in the intervention group, 54.3% (Beta = .543) of one score health belief gain was explained by attitude ($P < .001$; 95% CI: .275, .788), 53.3% (Beta = .533) by knowledge level ($P < .001$; 95% CI: .612, 1.808), and 47% (Beta = .47) by screening intention ($P = .001$; 95% CI: .116, .445). There was no significant association of health beliefs with neither knowledge level, screening attitude, subjective norms, perceived behavioural control, nor awareness among COMW in the control group. Furthermore, there was no significant association between participant's socio-demographic characteristics with changes of CCS health beliefs in both groups.

Effect of PLNav on CCS Uptake

At baseline (T0), all COMW from the intervention and control group had not previously screened for cervical cancer. At six-month follow-up (T2), a total of 32 (72.7%) COMW from the intervention group had screened, but only one COMW (2.3%) from the control group screened. The Repeated measures ANOVA with Greenhouse-Geisser correction across time showed that the effect of PLNav intervention on CCS uptake changes was statistically significant in the intervention group compared with usual care in the control group [$F(1, 43) = 100.39$, $P < .001$]. The effect of time on CCS uptake in the intervention and control groups was statistically significant [$F(1.64, 70.62) = 73.4$, $P < .001$], and PLNav intervention on CCS uptake interacted with time [$F(1.71, 73.59) = 71.0$, $P < .001$]. Across the time, there were significant mean differences between T0 and T1 (md = .3), $P < .001$, and between T0 and T2 (md = .4), $P < .001$. However, there was no significant mean difference between T1 and T2 (.034), $P = .183$. Refer to Table 2 and Figure 3. The linear regression was performed to determine the extent of the association of variables to CCS uptake. At six-month follow-

up in the intervention group, 84.5% of one score CCS uptake gain was explained by screening intention ($P < .001$; 95% CI: .057, .085), while 64.6% (Beta = 64.6) by subjective norms ($P < .001$; 95% CI: .067, .145), and 53.7% (Beta = .537) by perceived behaviour control ($P < .001$; 95% CI: .067, .194), and 53.6% (Beta = .536) of one's score screening uptake gain was explained by screening attitude ($P < .001$; 95% CI: .038, .111), and 29.9% (Beta = .299) by health beliefs ($P = .049$; 95% CI: .00, .084). In determining the influence of participant's socio-demographic characteristics on the changes of CCS uptake, it is found that after linear regression, 33.6% (Beta = .336) of one score gain of CCS uptake in the control group was explained by COMW's occupation ($P = .026$; 95% CI: .009, .136).

Discussion

The PLNav is an approach or instrumental in addressing individual, community, or structural screening barriers through health education, social support, and care.[57] In this present study, CHWs delivered a group health education session to COMW on cervical cancer and CCS. CHWs assisted COMW by escorting them to the screening health facilities, childcare, and scheduled appointment dates for screening. They provided counselling to women who missed the appointment dates, guided women with positive screening into referred facilities, and conducted follow-up care through face-to-face or home visits.[23,24,58]

Effect of PLNav on Awareness

PLNav increased COMW awareness in the intervention group compared to COMW in the control group. However, this increase was not associated with CCS uptake.

Effect of PLNav on the Knowledge Level of COMW

The finding indicates that PLNav effectively increased COMW knowledge in the intervention group at different times. However, there was no significant increase of cervical cancer knowledge level between T2 and T3 because most participants had already acquired adequate knowledge in three-month follow-up. This indicates that upon delivery of effective PLNav, three months are sufficient to promote a good outcome. The cervical cancer knowledge level among COMW remained increased even at six-month follow-up because the intervention was not delivered once but continuously delivered throughout the study period. Even though a group health education was provided once, counselling during follow-up was a part of health education that helped COMW retaining cervical cancer knowledge. Therefore, PLNav has demonstrated its effectiveness in promoting knowledge retaining. The high increased knowledge level at three-month follow-up among participants in the intervention group was influenced by an effective health education delivered by CHWs with counselling during the follow-up. Also, it is because CHWs lived in the same community of withdrawn potential participants in the intervention,[23,30,58] familiar with community culture,[30,58,59] and delivered a friendly health education concerning cervical cancer and CCS through native Swahili language.[59] The education session conducted in groups may have influenced the increase of knowledge level among COMW in the intervention group because participants shared their experiences and learned from each other.[23,24,27,30,49] Each CHW delivered the education to eleven participants, which is a reasonable number that CHWs could monitor the participation of every participant. During the health education session, participants were encouraged to ask more questions and give answers. Their full participation may have helped them understand the content. The session was not conducted hastily. Two hours was sufficient time to cover all content and conduct the discussion.[21,23,58,59] After the health education session, participants were provided with a half-page paper with information regarding cervical cancer and CCS that helped them have an individual reading at their homes.[21,23,63] Two weeks after health education, CHWs followed participants through phone calls or home visits.[23,24,58] During follow-up, CHWs delivered counselling to COMW to resolve their screening hindrances.[23,30] The usual care provided to the control group, which is ongoing awareness-raising campaigns by healthcare professionals, seemed not to increase women's knowledge of cervical cancer and CCS. This might be because some Tanzania healthcare providers deliver limited or wrong cervical cancer and CCS content to women due to their knowledge deficit/lack of information concerning cervical cancer and CCS. This finding is consistent with the previous findings reported that frontline medical providers of Tanzania were found to have a low level of cervical cancer knowledge and emphasized that inadequately trained healthcare providers is among the greatest barriers in cervical cancer prevention.[61] The awareness campaign is challenged because it is conducted at one time without follow-ups. Healthcare professionals may be perceived as strange, and their campaigns may not be culturally oriented to specific areas.

Effect of PLNav on Screening Intention

The screening intention refers to the women's level of readiness, desire, wish, or determination to uptake screening. As the word 'intention', the woman may intend or not intend to uptake screening. The higher the intention, the more women are ready to screen. According to TPB, the screening intention is predicted by attitude, subjective norms, and perceived behavioural control. The findings indicate that PLNav intervention effectively increased the screening intention among COMW in the intervention group. The attitude, subjective norms, and perceived behavioural control were the three strongest predictors of screening intention because their proportions are above fifty percent, which is supported with previous studies.[62,63] The health education delivered by CHWs, coupled with counselling

during follow-up care, resulted in an increased screening intention. This is supported by the previous study recommending that health education is an integral part of screening intention.[63,64]

Effects of PLNav on Health Beliefs of COMW

The PLNav seems effective in promoting positive health beliefs of screening uptake. The health education from CHWs helped COMW to have positive health beliefs about cervical cancer screening. It helped them believe that they were at risk of getting cervical cancer, the disease could threaten their lives and understood more advantages of screening, supported by the previous study demonstrating a significant correlation between knowledge and health beliefs.[65] That's is why the previous study recommended that an effective health education program address negative health beliefs among women.[66,67] The increased screening intention further influenced positive health beliefs among COMW in the intervention group, as it helped participants realize that the screening test is not painful, costly, and time-consuming. The follow-up care from CHWs may have contributed to increased positive health beliefs through counselling, which agrees with the previous study that the counselling-based program's implementation could modify women's health beliefs about cervical cancer screening.[68] The usual care COMW had a little increase in positive health beliefs because the ongoing awareness-raising campaign was not adequate to change women's health beliefs. One-time awareness campaign without follow-up may not be enough to change someone's health beliefs.

Effect of PLNav on CCS Uptake Among COMW

The finding indicates that PLNav was very effective in enabling COMW to screen for cervical cancer compared to usual care in the control group, which agrees with previous studies.[21,23,24,30,58,60,69] This high screening uptake among COMW in the intervention group is consistent with the previous finding that women's screening uptake was 83% after PLNav intervention.[70] The present study's increased knowledge level, screening intention, and positive health beliefs influenced COMW in the intervention group to uptake CCS, consistent with previous study.[71] However, screening intention had more influence compared to the rest. This is because; COMW in the intervention group had a significantly increased positive attitude, positive subjective norms, and positive perceived behavioural control. Identifying an increased knowledge level, screening intention, and positive health beliefs as the influence factors for screening uptake denotes that screening influence is a multifactorial matter. Health education alone or navigation services (escorting, transportation assistance, appointment scheduling, or follow-up) alone may not result in the desired outcome; instead, intervention should include both.[72] This poses a call for public health educators who think that public health education alone is functional; they have to know that women have misconceptions, emotions, and decision-making problems that sometimes may not be addressed by health education alone rather through other approaches.[73] In the present study, effective health education from CHWs increased knowledge levels and corrected existing misconceptions about screening. Follow-up care through counselling helped women understand the importance of screening, thus influencing screening uptake. This is consistent with the previous study indicating that cervical cancer and CCS knowledge determine the uptake of screening.[74] Even a simple, low-cost community-based education is adequate to achieve significant changes.[75] Increased health beliefs significantly influenced COMW to uptake screening, consistent with the previous study that reported that the increased health belief mean scores among women resulted in their CCS uptake. Immediately after health education, COMW in the intervention group were provided with a one-page visual paper showing pictures of a normal cervix and how it appears after being affected by cancer; this might have increased their health beliefs on perceived risks. An increased awareness did not influence participants to screen for cervical cancer. This calls for the government to know that the ongoing awareness-raising campaign is insufficient to promote screening practices unless other factors are implemented. COMW in the needy were escorted to the health facilities for screening, and CHWs, in collaboration with the screening nurse, ensured that participants did not spend much time waiting for the screening services because some COMW had a busy schedule. COMW from the intervention group did not decide to screen in the study period of six-month follow-up because some of them self-reported their busy schedule at their business or taking care of family issues, which is supported by previous study,[81] and others reported that their husbands were not ready for them to screen. The previous study reported increasing women's intention for screening uptake; husbands should receive health education about cervical cancer and CCS to improve support to their wives.[63] When husbands receive health education about CCS and HPV, they can support their wives by providing emotional support, including empathy, love, trust, and caring, instrumental support including all direct care need by the person, and informational support, including the provision of advice, suggestions, and information to accomplish the goal.[76] The screening uptake among COMW in the control group was very poor because they had inadequate knowledge of cervical cancer and CCS. They were not informed about cervical cancer causes, risk factors, signs and symptoms, prevention of cervical cancer, and advantages of cervical cancer screening. They had very little increased positive health beliefs at 6-month follow-up, little increased screening intention, and poor health-seeking behaviour even in other diseases or conditions. Many COMW from the control group who did not decide to screen self-reported that they did not decide to screen because they were not sick and had a busy schedule in their businesses or taking

care of their families, which is supported by the previous study indicating that women are reluctant to uptake screening because of the absence of signs or symptoms. Although COMW from the control group had good awareness about cervical cancer and CCS from the ongoing awareness-raising campaign at 6-month follow-up, they did not decide to uptake screening. The previous study supports this finding that although 93.8% of women had a higher level of awareness about CCS, only 13.9% had screened.[65] In this context, the study found that a higher level of awareness was not influencing women to screen for cervical cancer. This indicates that the ongoing awareness-raising campaign from healthcare providers does not focus on delivering in-depth information about cervical cancer and CCS rather helping women be conscious that cervical cancer exists and CCS services are available, which is not different from the Media community sensitization. Therefore, to ensure high screening rates among women, the ongoing awareness-raising campaign should be modified into a knowledge-raising campaign. Lack of follow-up in the usual care was another factor for most COMW decided not to uptake screening. In contrast to the intervention group follow-up care, the control group lacked counselling, escorting services, childcare, and screening appointments. While the previous systematic literature review found cultural norms as the strong facilitator to screening in the united states,[77] in contrast, the present study in Tanzania found that cultural norm is not among the facilitator for CCS uptake because more than 99% of participants had no language difficulty as they could speak the native language. Religion as a cultural norm showed no influence to participants to screen and even demonstrated no effect on screening intention. Male involvement in screening women was not a cultural factor because participant's partners were ready for their wives to be screened by male professionals.

Study Limitations

The community women (COMW) in the intervention group were not blinded due to the study's nature. The effect of health education, counselling, follow-up, and navigation care on CCS uptake was combined in the umbrella of PLNav. Therefore, the contribution of each in influencing women to screen was not established. The intervention and control participants were from the same ward, the intervention group women and the control group women may likely have shared the information, which might have caused data contamination. The sample size for this study was too small and most of participants (30%) refused to participate in the PLNav intervention that could have influenced some selection bias. Other limitations are self-report of the outcome measures and patient navigation approach missing informed decision-making.

Conclusion

PLNav was an effective approach to promoting cervical cancer screening knowledge, intention, and uptake. Health education alone delivered by CHWs may increase women's knowledge but not necessarily influence women to uptake cervical cancer screening. The integration of follow-up care and counselling was a fundamental element to encourage and provide confidence for women deciding to uptake CCS. The PLNav intervention quickly showed results in a short time, as the majority of participants in this study screened for cervical cancer and gained more knowledge level in the three-month follow-up. To further minimize the screening hindrances, husbands should be fully involved during the PLNav. Married women should attend health education and counselling sessions with their husbands. The husband will learn the advantages of their wives to uptake CCS, leading them to support their wives. To ensure the sustainability of PLNav within the communities, CHWs should be formally recognized by the government, and their motivation allowances should include in the national budget. It is time for the healthcare stakeholders/government to develop a national screening policy to guide everything about screening. Moreover, Tanzanian's nursing educational department should train more CHWs in various communities across the country. The utilization of this approach should move together with an improvement in the accessibility of screening. The dispensaries and health centres located within communities should be improved remarkably to ensure screening experts' availability and screening equipment. Further research should be conducted to assess the PLNav approach in promoting screening practices when men fully participate in the process. Moreover, future studies should focus on policies, registration, and recognition of CHWs within the country. Researchers may continue to discover other intervention approaches that simultaneously address multiple screening hindrances such as 'knowledge deficit, poor screening intention, and negative health beliefs'.

Acknowledgment

Authors would like to give thanks to the school of Nursing and Health of Zhengzhou University for support throughout the study. We acknowledge the contributions in the part of methodology from Dr Fabiola V. Moshi, a lecturer and Walter Cleophance Millanzi, the assistant lecturers at the University.

Authors' Contribution

All authors participated fully in developing and revising this manuscript

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Authors are grateful for research fund from the University of

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Ethical Consideration

University of Dodoma Research Ethical Committee in Tanzania approved the study protocol (UDOM/DRP/134/VOL IV/42). The participants signed the consent form before data collection and were reassured that their information would be confidential.

Registration Number and Name of Trial Registry

The trial registration: https://pactr.samrc.ac.za (PACTR202003570419141), registered on 26th February 2020.

Availability of Full Trial Protocol

The full trial protocol is available from the corresponding author upon reasonable request.

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Supplemental Material

Supplemental material for this article is available online.

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